

# Insulin pump Instruction manual

—PH900 series insulin pump



Zhengzhou Phray Technology Co., Ltd

[www.phray.com](http://www.phray.com)

**Hello!!!**

**Thank you for giving your trust in us.**

Thank you for purchasing a PH900 insulin pump. As a reliable partner, PH900 insulin pump with many clear- operating and ingenious functions makes you happy every time.

PH900 insulin pump provides a series of thought-out functions for you, as histogram basal rate setting, percentage temporal basal rate delivery, easy and simply operating for normal bolus, square wave bolus, auto-rewinding of screw, and auto-calculating of filled insulin. It is so convenient and easy-using that it can meet various customers.

Open your mind and live a more exciting life!!!

## Foreword

This manual aims to introduce the basic structure, functional characteristics, usage and related precautions of the PH800 series insulin pump. Therefore, please read this manual carefully before using the product for the first time.

This manual is suitable for users and medical workers, and can be used as a reference for engineering and technical personnel. This manual is compiled according to the status of the product at the time of publication. With the continuous improvement of the product, this manual will be revised accordingly when it is republished, and the revised items will not be notified. Under no circumstances should the data, illustrations, and descriptions in this manual be used as legal grounds to make demands on our company.

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## Important Notice

# Important Notice

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Warning: Before using your insulin pump, please read this entire instruction manual. If in doubt, please consult your attending physician, or contact PHRAY. Improper use of the pump, failure to comply with the instructions and important information in this manual, or improper handling of malfunctions may result in serious injury or even death.

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### Warning

- This insulin pump is specially designed for continuous subcutaneous infusion of insulin. Do not use the pump for other purposes. Do not use this product for transfusion of blood or blood components. This insulin pump can only be used under the guidance of this manual after strict training.
- This manual introduces how to use the insulin pump and how to deal with the failure. However, phray Technology does not provide any solutions and suggestions for diabetes treatment. When setting or using some special functions, it is necessary to cooperate closely with the attending physician.
- To avoid accidentally infusing insulin, detach the infusion line connector or pull the infusion needle from the puncture site before removing the old cartridge or infusion line. When the infusion line is connected to the body, it is absolutely forbidden to use the "push-exhaust" function of the insulin pump.
- As soon as a new cartridge or infusion line is loaded, blood glucose levels should be checked within 1 to 2 hours to ensure

## Important Notice

that the insulin infusion is correct.

- Improper disposal of batteries, electronic components, or contaminated (used) infusion lines can be a health hazard. Dispose of used batteries, infusion lines, other accessories, and life-end insulin pumps in an environmentally friendly manner and in accordance with relevant regulations.
- Don't stop your insulin pump therapy because you're sick, your body still needs insulin even if it's hard to eat. Follow the specific instructions given by your treating physician.
- If the patient is awake and able to care for the insulin pump, the insulin pump should be maintained. If insulin pump infusion is interrupted, an alternative insulin infusion must be provided.
- Please ensure that all caregivers around the user are familiar with the function of the insulin pump and are able to operate the pump and handle any malfunctions. Make sure they are familiar with any therapeutic information given to you by your treating doctor.
- Any damage to the threads on the cartridge compartment or edge of the infusion tubing may prevent the infusion tubing from being properly tightened onto the pump and may result in incorrect dosing.
- Because the basal rate scheme, carbohydrate coefficient (CHO), insulin sensitivity factor (sensitivity factor), target blood glucose, and some alerts are all time-dependent, all history is stored by time and date, so the time and date must be set correctly.
- The correct setting of the high-dose guide is very important, and you must set these items correctly with the assistance of

## Important Notice

your attending physician.

- Consult your treating physician to determine the carbohydrate coefficient (CHO factor), insulin sensitivity factor (sensitivity factor), and target blood glucose.
- Specialized training should be received on setting up and using basal rate infusions, all instructions should be read carefully, and the final implementation protocol should be agreed with the treating physician.
- Specialized training should be received in setting up and using high-dose infusions, all instructions should be read carefully, and the final protocol should be agreed with the treating physician.
- The total amount of insulin required per day should be agreed with the treating physician
- When replacing a new refill, it must be loaded according to the instructions in this manual to ensure that the refill is installed correctly.
- Make sure the connectors are securely connected. If the connection is not secure, insulin may leak from the connection, causing insufficient insulin infusion and possible infection due to contamination.
- Please check the remaining amount of medication before going to bed to ensure that there is enough insulin to be used during sleep, so as not to be unable to detect the low medication prompt and drug completion alarm issued by the insulin pump due to insufficient insulin during sleep.
- When an insulin pump is reworked, insulin must be infused by a different means until a new pump arrives.
- If your insulin pump falls, or hits a hard object, check

## Important Notice

carefully to make sure the pump is still working properly. Make sure that the display is normal and that the insulin pump and infusion line are connected. Inspect the infusion site to make sure it is still properly attached to the body (if it appears to be disturbed or the tape/dressing is cocked, it must be assumed that the insertion site is no longer correct and the infusion line replaced). Wrap a piece of tissue paper around the connection and check for wetting (moisture indicates a leak). If the pump housing is damaged (cracks, chips), the pump may no longer be waterproof.

- If the display has missing or incomplete characters, or if the insulin pump is not functioning properly, discontinue use immediately and contact your treating physician for advice on alternative means of infusion of insulin therapy.
- Only the infusion line with the PH2 interface in the "Infusion Pipeline for Disposable Insulin Pump" produced by Zhengzhou Phray Technology Co., Ltd. can only be used, otherwise it may lead to inaccurate inaccurate infusion dose or damage to the equipment.
- Can only be used with insulin refills in the table "Infusion Lines and Insulin Refill Information for Companionship".
- The insulin pump should be charged with an adapter that meets the requirements of IEC60601-1 standard, and the display is always on when charging. and there is a "CHARGING infusion is paused " is displayed.
- Avoid placing the insulin pump in an environment with a temperature higher than 42°C or lower than 0°C.
- Insulin freezes at around 0°C and deteriorates at high temperatures. When outdoors in cold weather, the insulin

## Important Notice

pump must be worn next to the skin and covered with warm clothing. When in a warm environment, measures must be taken to cool the insulin pump and insulin.

- Problems may arise if the insulin pump is operated at temperatures below 5°C or above 40°C, relative humidity above 90%, and atmospheric pressure below 70kPa or above 106kPa. If you find a problem, please stop using it temporarily.
- At an ambient temperature of 20°C, the time required for the ME device to go from the lowest storage temperature after use to the time it takes for the ME device to be ready for its intended use is 0S.
- At an ambient temperature of 20°C, the time required for the ME device to go from the maximum storage temperature after use to the time it takes for the ME device to be ready for its intended use is 0S
- Avoid strong magnetic fields (such as those produced by magnetic resonance imaging (MRI)), direct X-ray exposure, and ultrasound, as they can affect the working state of the insulin pump. If these conditions cannot be avoided, the insulin pump must be removed.
- Powerful household cleaners and chemicals can be damaged if strong household cleaners and chemicals are used directly or indirectly (e.g., on the hands) on the housing of an insulin pump.
- The insulin pump should be cleaned once a month, wipe it with a damp cloth soaked in water or a neutral detergent, and then wipe it with a dry cloth; do not use thinners, strong solvents, or bleach as cleaning agents.

## Important Notice

- Do not use steam or extremely hot water to sterilize the insulin pump; do not put the insulin pump in the dishwasher; exposing the insulin pump to high temperatures can damage its electronic components and cause damage to the insulin pump.
- Do not use insulin pumps in a hyperbaric chamber as they will affect the working condition of the insulin pump and may cause damage to the insulin pump.
- When the alarm system of the insulin pump is damaged (that is, when the vibration is turned on, the meal reminder does not vibrate), please stop using the insulin pump immediately.
- Always ask an endocrinologist or a professional doctor at the after-sales service point to check the use of the insulin pump and adjust the insulin dose.
- Try to avoid immersing the pump in water, because the impact or extrusion during long-term use and the tightness of the accessories may reduce the waterproof level of the insulin pump.
- In order to swim or participate in other water activities, be sure to temporarily remove the insulin pump and wear it immediately after the water activity.
- If accidentally dropped into the water, please use a soft and clean cloth to dry the insulin pump as soon as possible, and confirm that the insulin pump can work normally. If it is determined that water has entered the insulin pump or other abnormalities are found, blood glucose must be checked at this time, and insulin infusion should be infused by other methods if necessary. If you feel your blood sugar is too high or too low, or if you have any questions about your condition,

## Important Notice

please contact your doctor.

- When the infusion line is blocked, the maximum infusion pressure generated by the insulin pump should not exceed 200 kPa
- The insulin pump operates at moderate speed, and the blockage produces a pill dose of  $\leq 6u$ .
- When the battery is fully charged, the battery power can support the operation of the insulin pump at medium speed for no less than two insulin refills to complete the infusion.
- In the case of damage to the internal components, the device is powered off and restarted, and the time of saving the electronic memory function is permanently saved.
- The maximum capacity that can be transmitted in a single fault state is 2u.
- If the pump will not be used for a period of time, it should be turned off and the disposable battery should be removed for storage.
- Do not use this product for any other illegal purpose.
- When not in use, make sure the Bluetooth function is turned off.
- Pairing should be performed as infrequently as possible, preferably in a secure area where an attacker cannot actually observe passkey pairings and intercept Bluetooth pairing messages.
- Make sure that the portable device with the Bluetooth interface has a passcode set.
- Keep the account and password of the client and the pump connection account properly, and the password setting should not be too simple.

## Important Notice

- Try not to perform connection and data transmission operations in public places with many people.
- The power cord of the insulin pump and the infusion line used with it can cause a risk of strangulation.
- Infusion lines used with insulin pumps can pose a risk of strangulation.
- The palpable part of the insulin pump may have allergic reactions, causing contact damage to the human surface.
- Insulin pumps may also be unlocked by the wrong touch of children, pets, etc., leading to unintended use of the product. So make sure the product is kept away from unintended users. Accessories for insulin pumps include small components that pose a choking hazard for infants and young children
- Modification of this equipment is not permitted.
- Do not set up the insulin pump in bright light or in an environment full of cotton wool and dust.
- Please keep the device properly and operate it in strict accordance with the instruction manual.
- The lu (1 unit) used by this device is equal to 0.01 ml.
- Insulin pump with Bluetooth data transmission function transmitting frequency range: 2402MHz~2480MHz, 40 channels; modulation GFSK; Frequency characteristics: adaptive frequency jumping; EIRP: 0dBm
- Understand the meaning of the following symbols:



Attention! Check out the random file;



Type BF applied part.



# Important Notice

□ Class II equipment



Contains radio frequency emission identification parts



Model number



Serial number



Manufacturer



Date of manufacturer



Use-by date



European Union

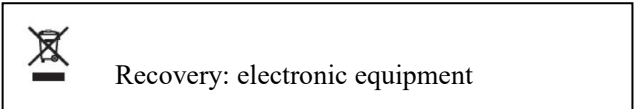


Follow the operating instructions

IP67 The dust protection rating is 6 and the water protection rating is 7



Complies with the requirements of the EU Council Directive 93/42/EEC on medical devices.



# Features and Structure

### Main Feature

PH900 series insulin pump is an intelligent syringe propulsion auxiliary device, the propulsion device is composed of insulin pump main unit and infusion pipeline. The main unit itself cannot complete the infusion of the medicinal solution independently, and a complete infusion system can only be formed after the infusion pipeline is installed.

The insulin pump adopts dual CPU mutual test control, and its safety performance fully meets the requirements of relevant standards. Among them, the PH920 series insulin pump has a Bluetooth data transmission function, which is connected to the client smart device to realize the data transmission between the insulin pump and the client device.

The equipment casing is also directly injection molded by engineering polymer materials with high strength and high impact resistance, so the overall waterproof performance and impact resistance can be better guaranteed.

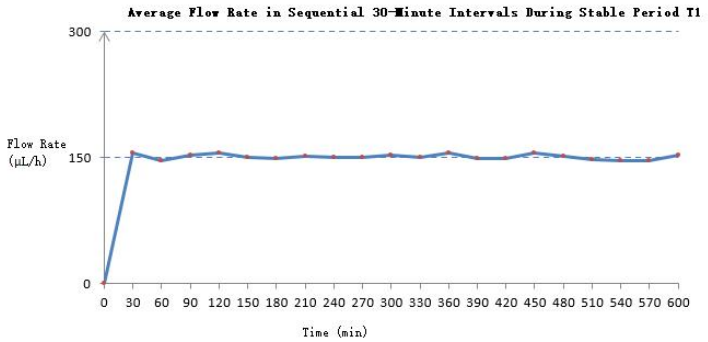
### Basic Feature

Accuracy of infusion volume: The tolerance for base rate infusion is  $\pm 5\%$  or  $\pm 0.01\text{u/h}$ , whichever is greater, and the tolerance for high-dose infusion is  $\pm 3\%$ .

Note: The basal rate infusion tolerance is  $\pm 0.01\text{u/h}$  at the limit ( $40^\circ\text{C}$ , 90%) and when operating at the minimum flow rate.

# Before Using

The following is a diagram of the infusion accuracy curve:



Description: Medium rate of base rate: 15u/h;  
Sampling interval: 5min;  
Period: T1-10 hours, T2-500 minutes.

# Before Using

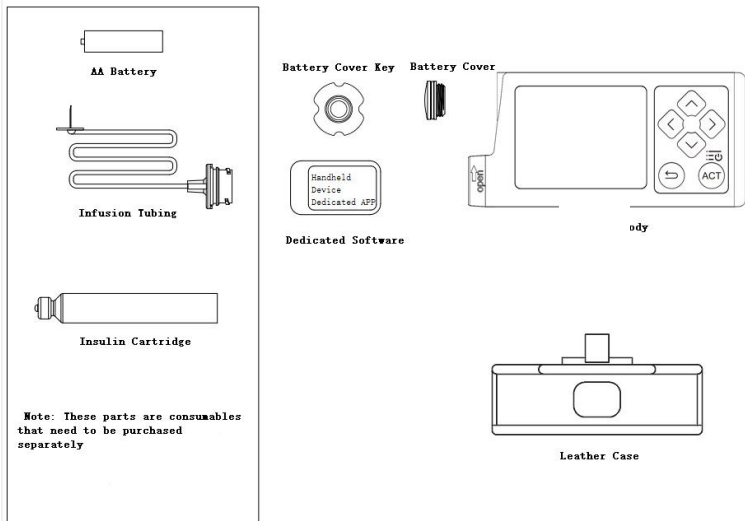
## Structural and Composition

The PH910 series insulin pump contains the main unit only

The PH920 series insulin pump consists of a main unit computer and client software.

Operating parts include:

- 1、 Main body
- 2、 Battery cover
- 3、 Battery cover key
- 4、 Client software (optional)
- 5、 Holsters
- 6、 No. 7 dry cell battery
- 7、 Infusion lines
- 8、 Insulin refills



## Before Using

# Scope of Application

The product is used in conjunction with adapted insulin refills and infusion lines for subcutaneous insulin infusion in diabetic patients.

This equipment is suitable for medical staff or trained and qualified individual users of various medical institutions;

The patient is the intended user

Contraindications to the use of the product:

- Diabetic patients who do not require insulin therapy.
- Patients in the acute phase of diabetic ketoacidosis and patients in the acute phase of hyperosmolar coma.
- Patients with hyperglycemia with severe circulatory disorders.
- Diabetic patients with allergies to subcutaneous tubing or adhesive tapes.
- Patients who are unwilling to have a long-term subcutaneous infusion tube or wear a pump for a long time, and who psychologically do not receive insulin pump therapy.
- Patients and their families lack the knowledge to properly grasp the user even after training.
- Diabetic patients with severe psychological disorders or psychiatric abnormalities.
- Young or elderly diabetic patients who are unable to take care of themselves and have no guardian.
- Diabetic patients who do not have self-glucose monitoring conditions or do not receive home self-glucose monitoring.

## Before Using

# Software release version

### Embedded software releases

The PH910 insulin pump has a software release number of 2-910;

The PH910E insulin pump has a software release number of 2-910E;

The PH910T insulin pump has a software release number of 2-910T;

The PH920 insulin pump has a software release number of 2-910;

The PH920U insulin pump has a software release number of 2-920U;

The PH920E insulin pump has a software release number of 2-920E;

The PH920T insulin pump has a software release number of 2-920T;


### Client software releases

PH900 series insulin pump is applicable to the client software release version number 2-0

## Before Using

# Terminology Introduction

**Confirm**—Press [ACT]Confirm selection or setting.

**Exit**—Press  Exit or save settings and exit.

**Pressing**—Keep pressing the insulin pump button.

**Scroll**—Press  Scroll through the screens.

**Status screen**—Displays the current working status of the insulin pump, including active functions, recent basal rate and bolus infusion, refill information, battery status, time, etc.

**Basal rate(Basal)** — An insulin pump setting that provides a continuous infusion of insulin to maintain blood sugar stability between meals and at night. It is a way to simulate the secretion of insulin in normal people in the non-eating state.

**Basal infusion** — Abbreviation for basal rate infusion, which provides continuous infusion according to pre-set different infusion requirements 24 hours a day to maintain a reasonable insulin infusion pattern in the body.

**Temporary Basal Infusion** —The abbreviation of temporary basal rate infusion, in the process of basal infusion, due to external or internal reasons, the infusion mode in which the dosage of basal infusion is increased or decreased by a certain percentage rate within the specified hours. This is a convenient setting to use in response to short-term fluctuations in insulin requirements due to occasional events or situations.

## Before Using

**Refer.Basal** — It means to enter the total amount of basal infusion medication and the calibration parameters of work and rest, and the system will automatically distribute the basal dose for each time period in 24 hours a day, making the setting of the basal rate more convenient and faster.

**Corre.Basal** — It means to enter the blood glucose deviation value, and the system will automatically complete the 4-hour or 24-hour basal rate correction.

**Normal Bolus** — Manually control the infusion mode to infuse a certain dose of medical solution in a short period of time.

**Square/Double Wave** — On the square/double-wave high-dose setting interface, when the proportion of the fast infusion setting is 0%, execute the square-wave high-dose; when the proportion of the fast infusion setting is greater than 0%, execute the double-wave high-dose.

**Bolus wizard** — A program that automatically calculates the amount of bolus infusion given the current blood sugar level, carbohydrate grams (CHO grams), target blood sugar level, carbohydrate coefficient (CHO coefficient), and insulin sensitivity coefficient (sensitivity coefficient).

**Target blood sugar** — Normal blood sugar levels.

**Blood sugar unit** — Blood glucose is measured in mmol/L or

## Before Using

mg/dl.

**CHO**—carbohydrate.

**Carbohydrate Factor (CHO Factor)**—When carbohydrate units are expressed in grams, the amount of carbohydrates that 1 unit of insulin can correspond to.

**Insulin Sensitivity Factor (ISF)**—1 unit of insulin lowers the amount of blood sugar.

**Supplementary infusion**—The amount of insulin needed to bring excess blood sugar levels back into the target range.

**Active liquid** —A large dose of insulin that has been infused into the body but has not been absorbed by the body for use.

**Alarm** —Vibrates to indicate that the insulin pump requires immediate attention.

**Alarm review** — Display various warning information records stored by the insulin pump.

**DKA** —Diabetic ketoacidosis.

**Diabetic ketoacidosis** — It is an acute complication of diabetes. It is acidosis triggered by a severe insulin deficiency caused by a sharp rise in blood glucose. It is a life-threatening condition that requires treatment in a hospital; It occurs when there is not enough insulin in the body and the cells in the body are unable to use glucose in the blood to produce

## Before Using

energy. The cells begin to burn the fat stored by the body for energy. When fat is burned, ketones are produced, and these ketones change the body's acid-base balance. Ketones can be detected by a blood test or urine test. If adequate insulin is not provided, DKA can occur within a few hours and can lead to coma or death.

**Gastroparesis** — A serious complication of slow digestion and absorption of food due to diabetes.

**Blood sugar level**—The amount of glucose in the blood. The average blood sugar level of normal people is 5.5mmol/L (100mg/d). Your treating doctor will help you determine a "target range" for your blood sugar levels.

**Pharmacokinetic properties** — Types of insulin used: short-acting insulin and rapid-acting (ultra-short-acting) insulin.

**High dose limit**—The maximum insulin dose that an insulin pump will allow in one bolus infusion. (set by doctor)

**Daily MAX** — The maximum insulin dose that the insulin pump is allowed to infuse in one day.

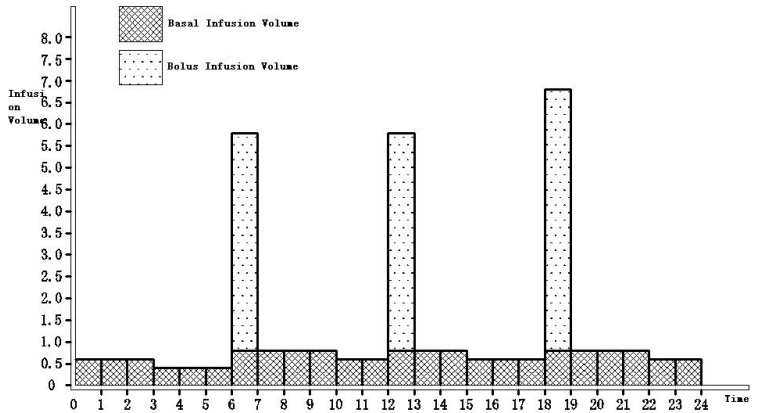
**Screw reset** — The insulin pump motor drives the plunger back to the start position for a new cartridge to be installed.

**Propulsion-Exhaust**—The process of removing air from an infusion line before it is inserted into the body.

## Before Using

**Refill**—A container for keeping insulin. The insulin cartridge used with the insulin pump has a capacity of 3ml.

**Daily total**—The total amount of medicine infused within 1 day is composed of two parts: the basic infusion amount and the high-dose infusion amount. (See below)



## Before Using

# Before Using

### **Prepare the insulin pump**

This leaflet provides information on setting up, using and maintaining your insulin pump. It is very important to read this manual carefully for using the insulin pump. If you have any questions, please consult your doctor or relevant trainers. Take this instruction manual with you and make sure you understand its contents thoroughly for safe and comfortable use of your insulin pump.

The version information of this manual is displayed on the back cover of the manual, if you have used this manual for more than 4 years, please contact Phray Technology, (or visit the website [www.phray.com](http://www.phray.com)) to see if there is an updated version of the manual available.

### **If you have questions, suggestions and comments .....**

If you have any questions, suggestions or comments about the insulin pump, please contact Phray Technology and provide the model and serial number of the insulin pump. If you have questions about your health or your insulin therapy, please contact your primary care physician for assistance.

Phray Technology provides 24-hour after-sales service, which can be contacted by phone or email (0755-27883210/[phray\\_sz@126.com](mailto:phray_sz@126.com)) The after-sales personnel are composed of technicians who have received professional training in the setting and operation of insulin pumps.

## Before Using

### First aid kit

A first aid kit should be carried with you to ensure that necessary items are readily available. Please inform family members, colleagues and friends of the location of the first aid kit. A first aid kit should contain the following items:

- Insulin syringes or pens (Insulin is temperature sensitive, so avoid storing it at extreme temperatures and replace it every month.)
- Rapid-acting or short-acting 3ml insulin cartridges
- Infusion line
- Blood glucose meter and test strips (make sure they are not invalid)
- AAA battery
- Medical identification card with contact information for your doctor or other important person

A copy of your insulin pump settings (basal rate, target blood glucose, CHO factor, insulin sensitivity factor, etc.).

Any special equipment that may be required in the emergency kit should always be discussed with the treating doctor.

### Practise

Before starting insulin pump therapy, it is important to become familiar with the insulin pump.

### Need to do

- Read this instruction manual.
- Complete the exercises required in this instruction manual.
- Practice the related settings of the base rate.
- Practice settings for bolus infusions.

## Before Using

### Notes

- Do not fit insulin-filled refills to your insulin pump during exercises
- Do not start insulin pump therapy without your doctor's supervision.
- Patients should keep in touch with medical staff and adjust the basic data of the insulin pump under the guidance of the doctor.
- Read the manual carefully before use and follow the instructions.
- Avoid strenuous exercise during use to prevent damage to the needle and infusion line.
- Check the working status of the insulin pump at any time, pay attention to the alarm, and avoid pipeline leakage, blockage, discount, etc.
- If the withdrawal time exceeds 1 hour, supplement insulin according to the instructions.
- Test blood sugar no less than four times a day (recommended after three meals and before going to bed), and contact medical staff in time if any abnormalities occur.
- When not in use, it is recommended to turn off the Bluetooth function.
- The client device should regularly check for updates and install protection software
- Insulin in unopened state should be stored at 2-8°C (refrigerated), and should not be frozen.
- If the activated insulin is not used up within 28 days, a new insulin cartridge also needs to be replaced to prevent

## Before Using

the insulin cartridge from becoming invalid.

- Insulin freezes at around 0°C and deteriorates at high temperatures. When outdoors in cold weather, the insulin pump must be worn close to your body and covered with warm clothing. Avoid exposing the insulin pump to ambient temperatures above 30°C, which can affect insulin activity. When the ambient temperature is too high or too low, the user must take the necessary measures to maintain insulin activity.
- The maximum dose of infusion under single failure condition  $\leq 2$  units.
- This product is intended for infusion of specified insulin only and should not be used for infusion of other fluids.
- Please be sure to use the consumables in the attachment "Infusion line and insulin refill information for use", the company will try its best to assist in dealing with the problems caused by the unmatched consumables, but does not assume various legal responsibilities caused by this.

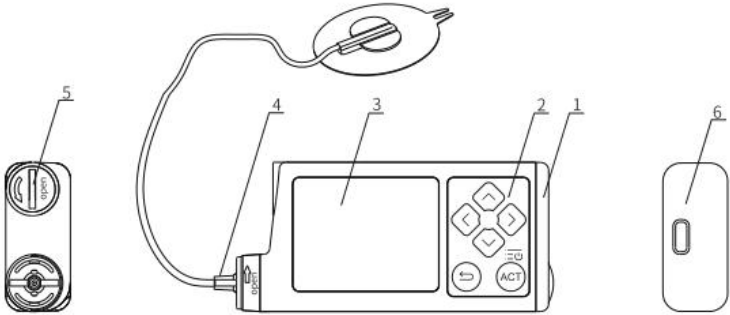
# Instructions for use

## Contents of this chapter

- Know the equipment
- Control panel
- LCD screen
- Steps for usage
  - Install battery
  - Infusion parameter settings
  - Screw reset
  - Install insulin refills and infusion lines
  - Exhaust
  - Inserting the infusion needle into the human  
body
  - Suspending or removing the insulin pump

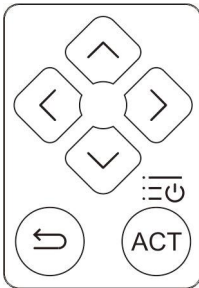
# Instructions for use



## Know the equipment





1. Fuselage body
2. Control panel
3. LCD screen
4. Infusion line
5. Battery cover
6. Charging port

## Control panel



  Up/down key, use this key to scroll up and down the screen menu, and also to change the size of the value. Press and hold this key for 2 seconds to achieve continuous scrolling of the screen or continuous change of values.

  Left/right key, use this key to select the screen menu

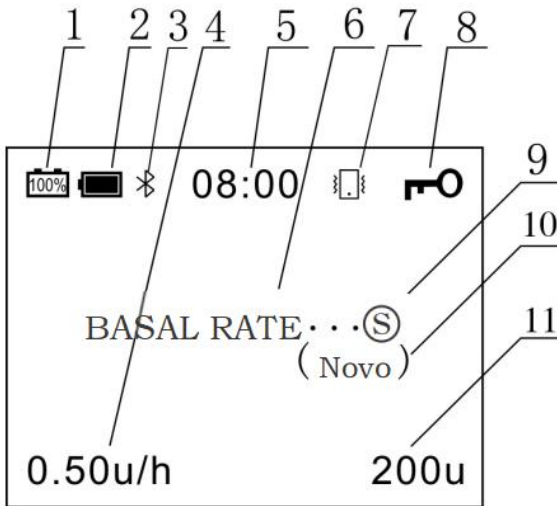
## Instructions for use

when changing the value interface.

↩ Back, exit key, use this key to return to the previous menu or exit and save this operation.

**ACT** Confirm the execution key and enter the "main menu" key.

### LCD screen



1. Lithium battery power information icon Through this symbol, you can know the current remaining power of the lithium battery at any time.



Note:

- When this icon keeps flashing, it means that the battery is about to run out, please charge it in time.
2. Dry battery power information icon Through this symbol,

## Instructions for use

you can know the current remaining power of the dry battery at any time.

Note:

- When this icon keeps flashing, it means that the battery is about to run out, please replace the battery in time.
3. When the Bluetooth current icon appears, the Bluetooth function is turned on.
  4. The infusion speed or remaining time display area currently displays "0.5u/h", indicating that the infusion is being performed at a rate of 0.5u per hour; when performing square wave infusion, if this area displays "60min", it means square wave There are 60 minutes remaining in the infusion.
  5. The clock shows the current time.
  6. Equipment working status display area Through the display in this area, you can know the current working status of the equipment. The general display contents include "Basic infusion...", "Temporary Basal Infusion...", "Large dose infusion...", "Square wave infusion...", "Screw reset...", "Exhausting ...", "Blocking!!!", "Pausing!!!" and other information.
  7. Vibrate When the current icon appears, the vibration function is turned on.
  8. Key lock icon When this icon appears, it means the key has been locked.Can press  Then press  within 3 seconds to unlock the keypad,This icon disappeared.
  9. The basal rate infusion program number currently executed by the basal rate program.

## Instructions for use

10. Refill Type--The currently selected refill type.
11. Remaining dose information --- the remaining dose in the current refill.

Note:

- When the medicine solution is lower than 20U, this icon will keep flashing, reminding that the medicine solution is about to be infused, please fill the medicine in time.

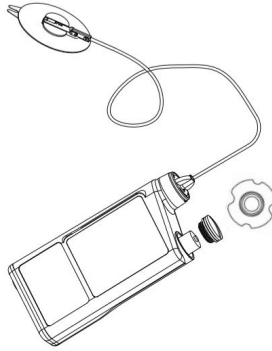
### Steps for usage

#### 1. Power supply

Fully charge the lithium battery or insert the front end of the battery cover key into the groove of the battery cover, turn it counter clock wise, and take off the battery cover; put a AAA battery into the battery compartment.

Lithium battery is preferred for power supply, and dry battery is used for power supply when the power of lithium battery is not enough to make the insulin pump work normally.

## Instructions for use



### Notice:

- The installation direction of the battery is the positive pole outward, that is the end of the battery with a small protrusion faces the direction of the battery cover.
- Be sure to use the battery cover key to open and close the battery cover, using other objects may damage the battery cover.

### 2. Power on

Long press **ACT** **ACT** turn on, the start-up interface appears on the display, followed by the main screen page.

### 3. Infusion parameter settings

Press **ACT** into “main menu”, press **▽** select “Basal rate”, and then press **ACT** enter “Basal rate menu”, press **ACT** can enter “Basal rate setting” Then press the **◀**、**▶** select the set time, press **◊**、**▽** select to change the value of the selected item, After setting



## Instructions for use

press **ACT** exit. (For details, please refer to "Basic Rate Settings")

### 4. Screw reset

Press **ACT** into "main menu", press **ACT** select "Charge - Exhaust", and then press **ACT** enter "Charge - Exhaust menu", this time press **ACT** Start to execute "screw reset". The reset time generally takes a few minutes, and at this time, other charging preparations can be done. (For details, please refer to "Charging - Exhaust")

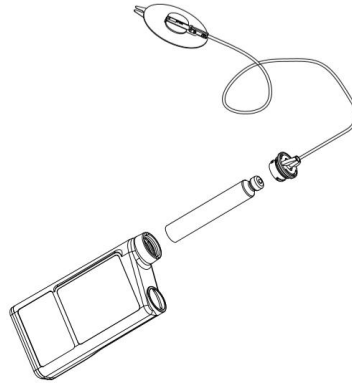
Notice:

- The reset process cannot be stopped manually, nor can any other operations be performed during this time.

### 5. Install the cartridge and infusion line

Rotate counterclockwise to remove the infusion line, put the unused insulin cartridge into the cartridge compartment, and install the infusion line on the insulin pump in a clockwise direction.



## Instructions for use



### Notice:

- Before loading the refill, please make sure that the insulin pump screw has been reset successfully.
- Only insulin refills with limited specifications can be used (only refills recommended by the manufacturer can be used).

## 6. Exhaust

Enter "Charging-Exhaust", press select  "propulsion-exhaust", then long press  to start "propulsion-exhaust".

### Notice:

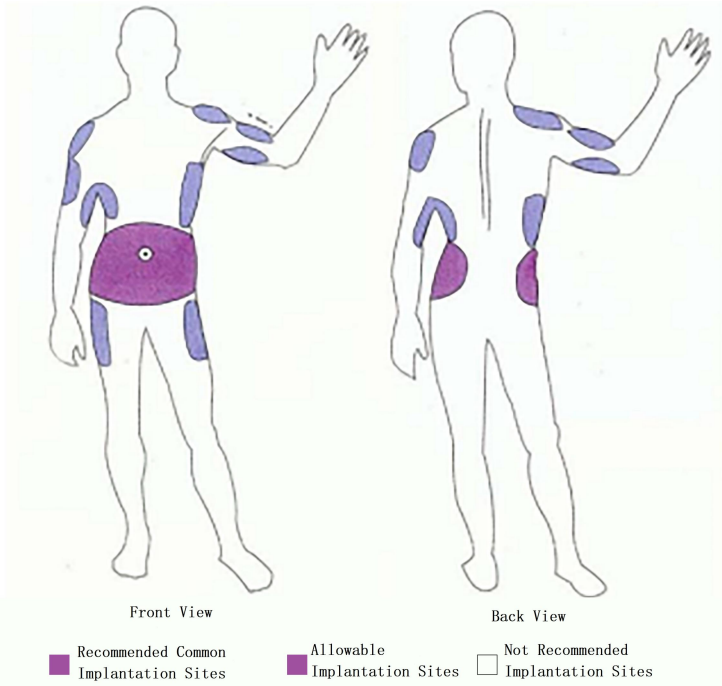
- Before performing "push-exhaust", the infusion line must be separated from the human body.
- The air bubbles in the insulin cartridge need to be completely discharged.

## Instructions for use

### **7. An infusion needle is implanted into the body**

please wash your hands first, and use alcohol to disinfect the recommended parts in the figure below; hold the infusion needle handle at the end of the infusion line, and carefully remove the protective cover of the needle; use your thumb and forefinger to squeeze around the injection site Then insert the infusion needle under the skin, and fix the handle of the infusion needle on the skin with an applicator; use tape to fix the pipeline 10 cm away from the infusion needle to prevent the infusion needle from falling off when pulled by external force.

## Instructions for use



### 8. Removal of infusion tubing for single-use insulin pumps

Carefully uncover the patch that fixes the infusion needle; hold the handle of the infusion needle with one hand, gently press the body tissue near the injection site with the other hand, and pull out the infusion needle perpendicular to the skin; rotate the connector of the infusion line in the opposite direction when it is inserted, to separate the connector from the insulin pump, take out the cartridge, screw the cap of the cartridge compartment clockwise to the insulin pump, and dispose of the discarded infusion line in the correct

## Instructions for use

way.

Statement:

Inexperienced responsible parties must contact their local authorities to decide on the proper disposal of discarded potentially biohazardous components and accessories.

Notice:

- Change the infusion line at least every 72 hours.

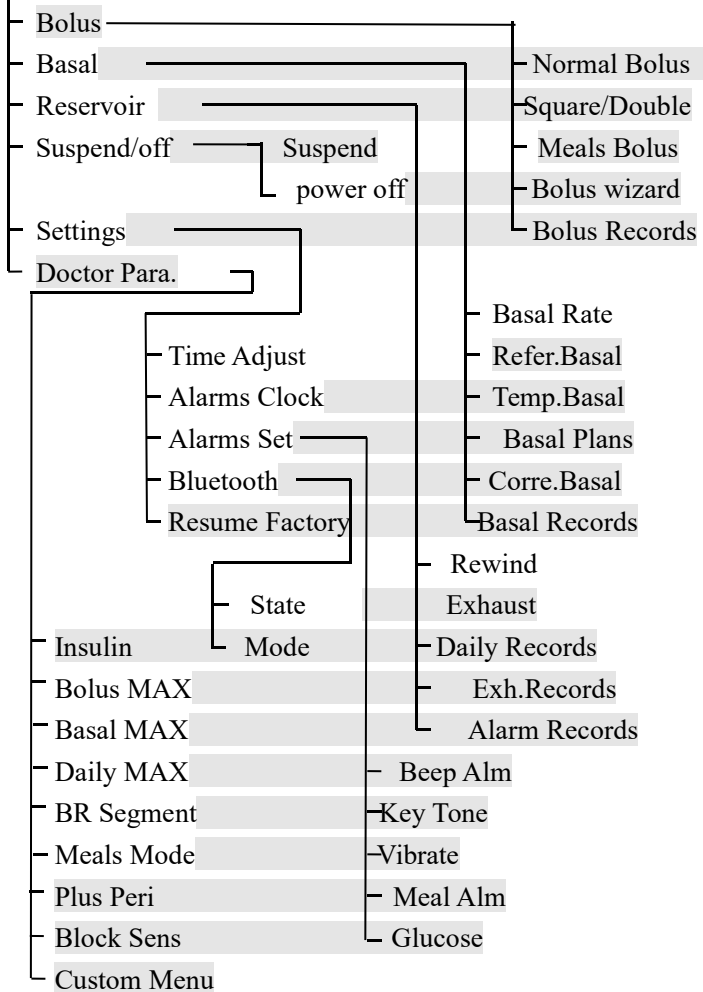
### **9. Suspending or removing the insulin pump**

Execute the "Infusion Pause" function and remove the insulin pump.

# Basal infusion

## Main menu

### Menu



(Bolus wizard、Corre.Basal、Alarms Clock、Vibrate、Bluetooth off by default)



# Basal infusion

## Contents of this chapter

- **Overview of the base rate settings**
- **Base rate operations**
  - Basic rate setting
  - Basic rate quick setting
  - Temporary base rate setting
  - Basic rate plan
  - Basic rate review

# Basal infusion

## Base Rate Overview

The basal rate infusion is an insulin pump-specific way of simulating insulin secretion in normal people without eating. The body also needs basal insulin to maintain target blood sugar levels when meals are skipped. Different people's basal total accounts for a different ratio of the total insulin required throughout the day, ranging from about 35% to 60%.

Insulin pumps can be infused with two preparations of insulin: short-acting and rapid-acting (ultra-short-acting) insulin. It takes 2 to 4 hours for the short-acting insulin to reach the peak hypoglycemic effect time after infusion into the subcutaneous tissue, and the peak hypoglycemic action time for the rapid-acting (ultra-short-acting) insulin to be infused into the subcutaneous tissue is 1 to 1.5 hours. Therefore, when setting the basal rate, the basal rate that needs to be set for each time period should be uniformly advanced by 1 to 4 hours, so that the best hypoglycemic effect can be achieved within the required time.

Accidents, trauma, illness, women's menstrual cycles, and emotional upheavals in life can cause fluctuations in insulin requirements, so don't change your basal rate based on the results of a blood glucose monitor. Simultaneous blood glucose measurements should be repeated several times to ensure that

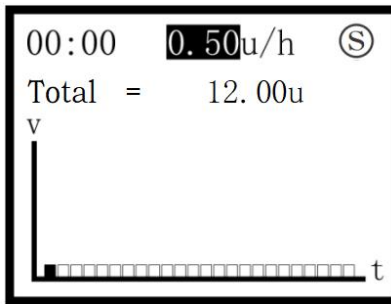
## Basal infusion

the basal rate adjustment is accurate.





### Base rate operation

#### Base rate setting

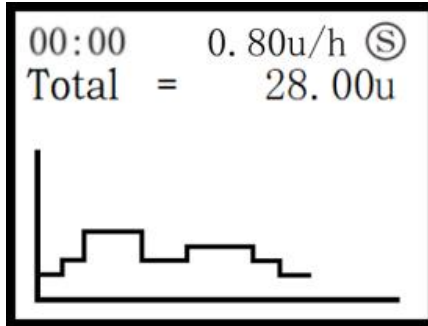
Main Menu>Basic Rate>Basic Rate Setting



(24 时段 Segment)

1. The picture on the right is the basal rate setting screen of the 24-segment method. The 24 columns represent the 24 infusion periods in a day, and the height of the columns represents the infusion value in the corresponding period. The factory default setting is 0.5 units for 24 time periods.
2. "00:00" indicates that the currently selected time period is from 0 o'clock to 1 o'clock; "0.5u/h" indicates that the infusion rate of this period is 0.5 units per hour; "12.0u" indicates the sum of the basic volume of 24 periods. Press  or the  key to switch between each session in turn, and press  or  to change the infusion value for each session.

## Basal infusion



(48 Segment)





3. The picture on the right is the 48-segment method basal rate setting screen. The entire curve represents the change of the infusion rate within 24 hours of the day, and the height of the curve represents the infusion rate in the corresponding period.
4. Press  $\diamond$ 、 $\diamond$  or **ACT** to select time parameter, press  $\diamond$ 、 $\diamond$  can fix the size of each parameter value. When press  $\diamond$  increase time, The infusion speed of this period will be automatically assigned according to the speed on the left, when press  $\diamond$  increase or decrease time, The infusion rate during this period will not be changed, and the infusion rate needs to be adjusted manually.
5. At 48 segments, "00:00" means that half an hour from now on is a timing segment, and 0.8u/h means that the infusion rate during this period is 0.8 units per hour.

Notice:

- The setting range of basic infusion rate is: 0 ~

## Basal infusion

35u/h, medium speed 15u/h. The adjustment accuracy is 0.1u/h at 24 hours, and 0.05u/h at 48 hours.

- 24-Segment, press the 、 button for the first time, and the infusion value of the current period will automatically take the set value of the previous period; Press 、 keep the key, the set value will be changed continuously, which can increase the set speed.
- In the state of 48 periods, if it is only necessary to adjust the infusion rate of individual periods, the time-decreasing method can be used.

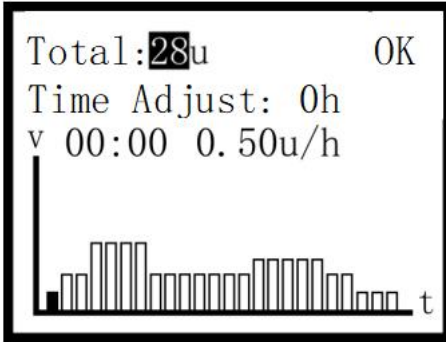
### Basic rate quick setting (optional)

The insulin pump provides a quick setting function of the basal rate, that is, the insulin pump can automatically complete the 24-hour basal rate setting according to the daily basal total amount and the correction parameters of the work and rest time.

Menu location: Main menu - Base rate - Quick setting

of base rate

## Basal infusion



Enter the base rate quick setting screen, press  $\diamond$ 、 $\nabla$  to correct the value of the anti-white item, press **ACT** to switch the item pointed by the anti-white cursor, when "confirm" the anti-white, press the **ACT** key to execute the base rate quick setting, after the execution of the "basic rate line quick setting", you can enter the base rate setting screen to view or correct the basic infusion value of each period again. The specific corresponding values of the base rate are shown in (Appendix 1).

### Notice:

- The 24-segment time corresponds to the 24-segment method base rate database, and the 48-segment time corresponds to the 6-segment method base rate database.
- The impact of work and rest time correction parameters on automatic allocation should be clarified.
- The fast setting data are for reference only, please consult the attending physician for the specific

## Basal infusion

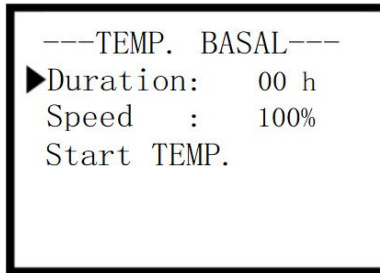
medication plan.

### Temporary rate setting (optional)

Temporary basal rate infusions are a convenient way to set up in response to short-term changes in insulin requirements caused by certain impromptu events or situations.

The main menu > base rate > base rate settings

### Start provisional base rate

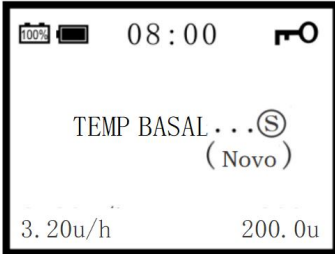


After entering the temporary base rate setting screen, can press ◀, ▶ to select the two parameters of duration and temporary rate, press ▲, ▼ to adjust“▶”refers to the item, press **ACT** to confirm activation of the selected item, When the value of the selected item is highlighted, can press adjust the size of the value, when“▶” pointing to "Start Temporary Basal Infusion", press **ACT** The Temporary Basal Infusion will be started directly.

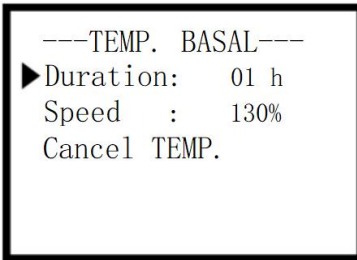
The adjustment range of "Duration" is: 0~24 hours; the adjustment range of "Temporary Rate" is: 0~200%.

Temporary Basal Rate Infusion Screen:

## Basal infusion



Cancel clinical base infusion:



During the clinical base infusion process, if you need to stop midway, you must enter the clinical base rate setting screen again, press ◀, ▶ to adjust “▶” to "Cancel Temporary Basal Infusion" option, then press **ACT** to confirm.

Notice :

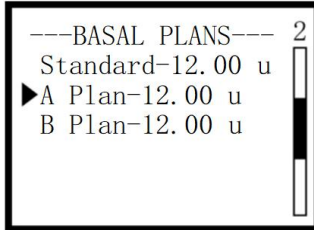
- The percentage rate of the provisional rate is the ratio of the actual infusion rate relative to the basal rate for the same period.

## Basal infusion

### Basic rate plan (optional)

The insulin pump can pre-store multiple set basal infusion schemes, so that they can be called in time when needed.

Main Menu > Base Rate > Base Rate Scheme



In the basic scheme menu, can press  $\uparrow$ 、 $\downarrow$  to choose the basic plan you need, press **ACT** to enter the program information screen, can press  $\uparrow$ 、 $\downarrow$  to view the infusion rate for each period, In the program information screen press **ACT** to set this protocol as the current infusion protocol.

Notice:

- It can only be modified after setting the pre-stored scheme as the current basic scheme.

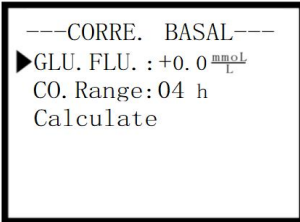
### Corrected base rate (optional)

When using the insulin pump for the first time and during normal use, it is sometimes found that the blood sugar is often higher (or lower) than the target blood sugar value, which indicates that the current basal infusion plan needs to be adjusted. This insulin pump provides automatic With the correction function, you only need to provide the current blood glucose deviation value, and the insulin pump will automatically calculate a new basal rate plan for reference,

## Basal infusion

which greatly facilitates the adjustment of the basal rate.

Main Menu > Basal Rates > Corrected Base Rates



Enter base rate, can press  $\leftarrow$ 、 $\rightarrow$  to adjust ▶ refer item,

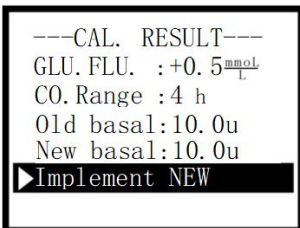
press **ACT** to confirm select item, when the item value

becomes highlighted, then can press  $\leftarrow$ 、 $\rightarrow$  to adjust the

value, and then press **ACT** to confirm. Press  $\leftarrow$ 、 $\rightarrow$  to

adjust ▶ Point to the "Perform Correction Calculation"

option,press **ACT** to Confirm this setting.



Notice:

- The data obtained from the calibration calculation are only for treatment reference, and the specific

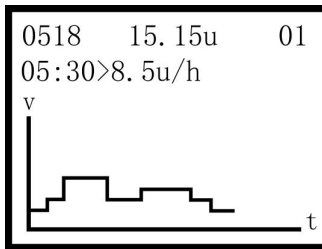
## Basal infusion

medication regimen should be consulted according to the condition.

- "+" indicates that the measured blood glucose value is higher than the target blood glucose value, and "-" indicates that the measured blood glucose value is lower than the target blood glucose value.



## Base rate review

Main Menu > Base Rates > Base Rate Review



The base rate review will save the latest 500 base rate correction information, which can be used as a reference for future settings or treatments.press

ACT can view the base rate settings executed on

different days , press   can be viewed for each infusion period of the same basal rate setting.

If the number of retrospectives exceeds 500, the retrospective records with older dates are automatically overwritten.

# Bolus Infusion

## Contents of this chapter

- Bolus General Usage
- Bolus setting
  - Manual large dose (regular mode)
  - Manual large dose (three meal mode)
  - Square/Double Wave
  - Three meals preset
  - High Dose Review
  - High Dose Wizard
  - Overview of the High Dose Wizard
  - Bolus Dose Wizard Set up
  - High dose wizard use

# Bolus Infusion

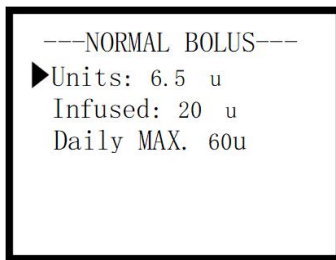
## Bolus General Usage






- Infuse before eating.
- Supplementary infusion when correcting hyperglycemia.




### 1. Bolus setting

#### Manual bolus

Main Menu > Bolus > Manual Bolus (Normal Mode)



Enter Bolus screen, can press   to change the infusion value for this bolus infusion, press  to confirm infusion, this time will show "pressACT to start infusion, press  return", press  to confirm will start perform a manual bolus infusion.

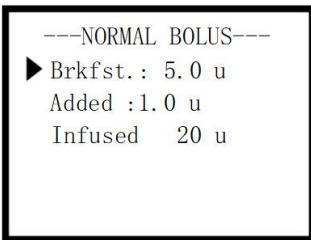
During manual bolus infusion, press  can stop infusion. During the infusion, can press  and press  to lock the keyboard, prevents accidental button presses from terminating the infusion.

# Bolus Infusion

Notice:

- Every time you enter the high-dose setting screen, the system will automatically obtain the preset value of the three meals corresponding to the time period to facilitate the setting.

Main Menu>High Dose>Manual High Dose (Three Meals Mode)



Enter manual high dose screen, press **ACT** to confirm infusion, also can press **◀**、**▶** to adjust the “▶” value, and then press **ACT** to confirm activate selected item, When the value of the selected item is highlighted, can press **▲**、**▼** to adjust the value, and then press **ACT** to confirm infusion.

During manual bolus infusion, press **↶** to stop infusion,

The insulin pump has a three-meal mode, which can more conveniently and quickly perform three-meal large-dose infusion.

## Bolus Infusion

The three-meal mode is a mode that prescribes a large-dose infusion before three meals a day and quickly performs a large-dose infusion. It is generally suitable for users who eat three meals a day regularly.

The infusion time corresponding to the large dose of three meals (automatically adjusted with the calibration parameters of work and rest)

Breakfast: 05:00~10:45

Lunch: 10:45~16:30

Dinner: 16:30~23:00

Notice:

- The default value of three meals can be adjusted in the three meals preset menu.
- The impact of the work and rest time correction parameters on the corresponding time periods of the three meals should be clarified.
- If you miss the infusion period of three meals, you can perform the infusion with additional volume
- Supplementary dose is used to cope with temporary blood sugar rise or a small amount of extra meals.

### **Square wave bolus**

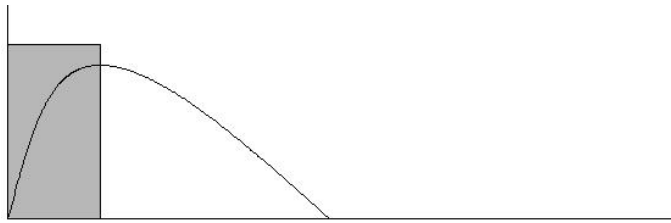
Square wave high-dose infusion refers to the uniform infusion of a set amount of insulin in the form of pulse infusion

# Bolus Infusion

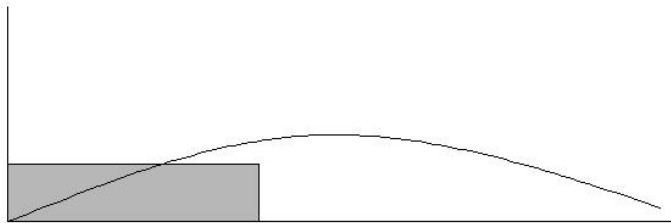
within a specified period of time, which is suitable for slow eating or slow digestion caused by gastroparesis and high-fat food. If blood glucose drops too rapidly with manual bolus infusion, square wave bolus can be used.

The figure below depicts the difference between manual bolus infusion and square wave bolus infusion,

■ in the figure indicates the way of large dose infusion, represents the action curve of large doses of insulin after entering the human body. ① Manual bolus infusion ② Square wave bolus



① Manual Bolus Infusion Mode




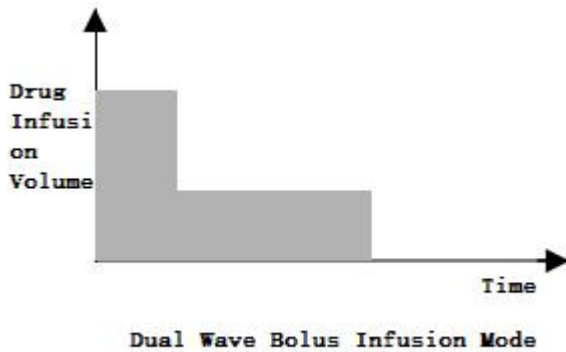
② Square Wave Bolus Infusion Mode

# Bolus Infusion

## Double wave high dose

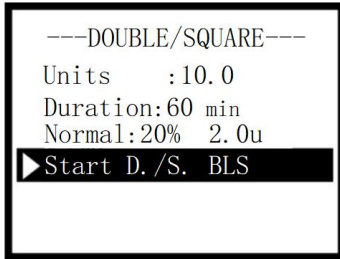
Dual-wave bolus combines the features of a bolus and a square wave bolus, and can be used for meals that include fast-absorbing foods and foods that take longer to absorb.

The figure on the right depicts the double-wave high-dose infusion method, and  in the figure indicates the high-dose infusion method.



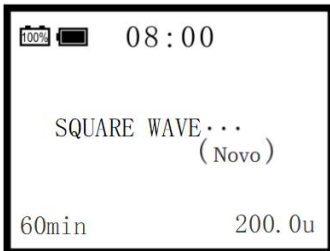
Main Menu>High Dose>square/double-wave high-dose

# Bolus Infusion



After entering the square/double-wave high-dose screen, you can press to adjust the item indicated by "▶". When the value of the selected item is highlighted, you can press to adjust the value. When "▶" points to "start square/Double-wave infusion", press to start square/double-wave infusion directly.

## Square/Double Wave Infusion Screen Status



The minimum infusion volume of square/double wave high dose is 2u;

The adjustment range of the infusion time is: 0 to ~ 240 minutes.

## Bolus Infusion

---DOUBLE/SQUARE---

Units :10.0  
Duration:60 min  
Normal:20% 2.0u

▶Cancel D./S. BLS

During the square/double wave infusion, if you need to stop midway, first enter the square/double wave high dose screen, at this time the "start square/double wave infusion" has been replaced by "cancel square/double wave infusion". Instead, press ◀, ▶ to adjust "▶" to "Cancel Square Wave Infusion" option, and press **ACT** to confirm.

## Three meals preset

Main Menu>Large Dose>Three Meal Presets

---Meals/Bolus--- 2

Breakfast: 5.0u  
▶Lunch : 6.0u  
Supper : 5.0u

It is used to set the default value of the large dose, and the reasonable setting makes the pre-meal infusion more convenient.

# Bolus Infusion

## High Dose Review

The bolus infusion information can be viewed on the bolus review screen, which records the date, time and infusion volume of the past 500 bolus infusions.

Main Menu > High Dose > High Dose Review

---Bolus RECORDS---		
0313	08:00	>10.0u
0312	18:00	>8.0u
0312	12:00	>8.0u
0312	08:00	>10.0u
0311	18:00	>8.0u
0311	12:00	>8.0u

You can scroll to view by press 、

Notice :

- If the bolus infusion is terminated during the bolus infusion, the bolus infusion review will only record the actual amount infused.

## Bolus Wizard (optional)

### Overview of the High Dose Wizard

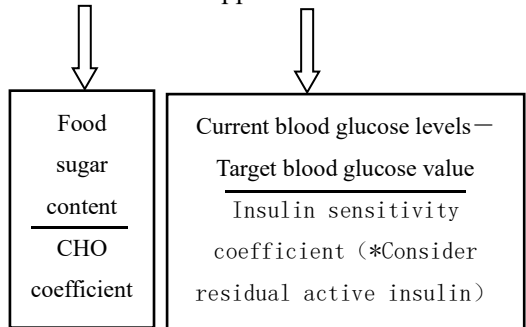
The High Dose Wizard can calculate the dose of large infusions more scientifically and accurately, so that you have

## Bolus Infusion

more freedom to eat and better blood sugar control. Mastering the high-dose wizard will enable insulin pump users to truly achieve: freedom of eating; freedom of life; Blood sugar control is fast, smooth, and safe.

The effect of high-dose infusion on the human body is divided into two parts: meal high-dose and supplementary high-dose. A meal bolus is a large amount of insulin infused before a meal in order to suppress the sharp rise in blood sugar levels after eating. Supplementary large doses are used to correct the insulin required for hyperglycemia above the target blood sugar level, which can be before or after meals or at any time point.

$$\text{Total bolus} = \text{Meal bolus} + \text{Supplement bolus}$$



**Residual active insulin** refers to the residual high-dose insulin that has been infused into the body and has not exerted its biological effect as determined according to pharmacodynamics. The concept of residual active insulin was used to establish a

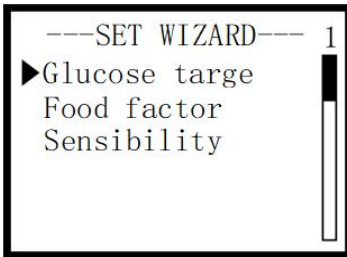
## Bolus Infusion

conservative bolus estimate to prevent overinfusion of the estimated bolus. Active insulin is considered according to pharmacodynamics, which can better control blood sugar and reduce the incidence of hypoglycemia.

### Information needed by the High Dose Wizard

To use the high-dose wizard for intelligent calculation, you must first determine the relevant physiological indicators, including: target blood sugar, CHO coefficient, and insulin sensitivity coefficient, and each indicator is constantly changing within 24 hours a day.

Main Menu > Bolus Dose > Bolus Dose Wizard > Setup Wizard

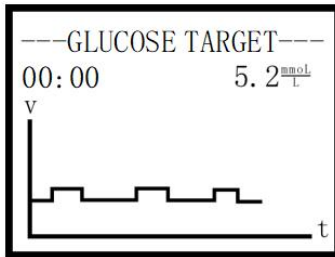


**The target blood sugar level** is used to set the detailed ideal blood sugar level at each time period within 24 hours a day. This insulin pump allows setting a target blood sugar level every 30 minutes at most. The blood sugar level of normal people fluctuates between

## Bolus Infusion

3.4-7.8mmol/L. The patient's control target can be below 11.1mmol/L, please ask the doctor to determine your target blood sugar value according to the condition.

Main Menu > Bolus > Bolus Wizard > Setup Wizard > Target Blood Glucose



The whole curve represents the change of the target blood glucose in 24 hours throughout the day, and the height of the curve represents the target blood sugar in the corresponding period. "00:00" indicates that the selected time period is from 00:00 to 00:30. "5.2 mmol/L" indicates that the target blood glucose for this period is 5.2 mmol/L.

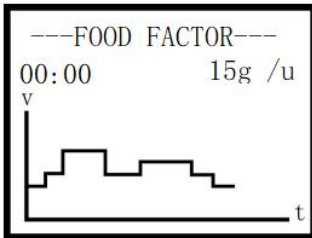
Press  $\diamond$ 、 $\diamond$  to select time parameters, and press  $\diamond$ 、 $\diamond$  to correct the size of each blood sugar value. When pressing the  $\diamond$ 、 $\diamond$  to correct the blood sugar level, press the **ACT** and the target blood sugar level for the next period will be automatically assigned according to the blood sugar level on the left.

## Bolus Infusion

Please set the target blood sugar for each time period in turn according to the doctor's advice, and the obtained curve is the 24-hour target blood sugar curve.

**The carbohydrate factor** is the ratio of sugar to insulin, that is, the number of grams of sugar that can be eaten per lu of insulin injected. The carbohydrate ratio is used to set the detailed carbohydrate ratio for each time period within 24 hours a day. This insulin pump allows setting a carbohydrate ratio every 30 minutes at most.

Main Menu > High Dose > High Dose Wizard > Setup Wizard > Carb Factor



The whole curve represents the change of the carbon coefficient within 24 hours of the day, and the height of the curve represents the value of the carbon coefficient in the corresponding period. "00:00" indicates that the selected time period is from 00:00 to 00:30. "15 g/u" means that the carb coefficient for this period is 15 g/u.

Press  $\diamond$ 、 $\diamond$  to select the time parameter, and press  $\diamond$ 、 $\diamond$  to modify the value of each parameter. When pressing  $\diamond$ 、 $\diamond$  to correct the carbon water factor, press **ACT** the carbon water factor in the next period will be automatically assigned

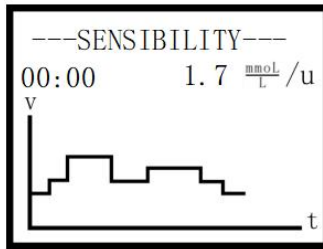
## Bolus Infusion

according to the carbon water factor on the left.

Please set the carbohydrate coefficient value of each time period in turn according to the doctor's advice, and the obtained curve is the 24-hour carbohydrate coefficient curve.

**The carbohydrate factor** is the ratio of sugar to insulin, that is, the number of grams of sugar that can be eaten per lu of insulin injected. The carbohydrate ratio is used to set the detailed carbohydrate ratio for each time period within 24 hours a day. This insulin pump allows setting a carbohydrate ratio every 30 minutes at most.

Main Menu > High Dose > High Dose Wizard > Setup Wizard > Carb Factor



The whole curve represents the change of the sensitivity coefficient within 24 hours of the day, and the height of the curve represents the sensitivity coefficient value of the corresponding period."00:00" indicates that the selected time period is from 00:00 to 00:30. "1.7mmol/L/u" means that the sensitivity coefficient is 1.7mmol/L/u.

Press  $\diamond$ 、 $\diamond$  to select the time parameter, and press  $\diamond$ 、 $\diamond$  to modify the value of each parameter. When pressing  $\diamond$ 、 $\diamond$

## Bolus Infusion

to modify the sensitivity coefficient value, press ACT to automatically assign the sensitivity coefficient value in the next period according to the sensitivity coefficient value on the left.

Please set the sensitivity coefficient value of each time period in turn according to the doctor's advice, and the obtained curve is the 24-hour insulin sensitivity coefficient curve.

### **Infusion using the bolus guide**

After completing the wizard setting, enter the use wizard menu and set the corresponding parameters, you can start the large dose wizard estimation.

### **Using the bolus wizard requires 2 parameters**

- Current blood sugar level
- Grams of carbohydrates eaten

The current blood sugar level can be measured, but the amount of carbohydrates eaten needs to be estimated, so you should learn to calculate the sugar content in food.

### **How to Calculate Grams of Carbohydrates**

The weight of some food is the weight of the sugar it contains, such as: candy, lollipop, and the sugar in some food is only a part of the total weight, and the sugar content can be calculated

To use the following three methods:

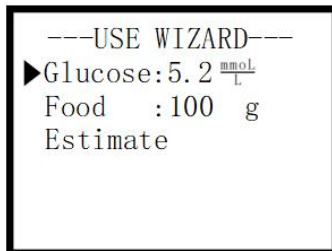
- Obtain the sugar content directly from the instructions on the outer packaging of the food    Some food outer

## Bolus Infusion

packaging is printed with nutritional labeling, including calories, the respective contents of sugar, protein, and fat contained in each package.

- Look it up from the Nutrition Facts table There are many books about nutrition, such as "Chinese Food Composition List" published by the Institute of Food Nutrition and Hygiene, Chinese Academy of Preventive Medicine. from which To quickly find out how many grams of sugar are contained in every 100 grams of this kind of food.
- Calculation using sugar factor table The sugar factor of various foods is recorded in the sugar factor table. The calculation formula is as follows: weight of food  $\times$  sugar factor of food = weight of sugar in the food (grams) input parameters to estimate the large dose value.

Main Menu > High Dose > High Dose Wizard > Usage Wizard




After entering the wizard screen, press  $\diamond$ 、 $\diamond$  to adjust the item indicated by "▶". When the value of the selected item is



## Bolus Infusion

highlighted, you can press **ACT** to enter the current blood sugar and **ACT** primary carbohydrate value, and then press to Adjust the item indicated by "►" to "Execute Estimation" and press **ACT**, the program will automatically calculate the amount to be infused this time.

---ESTIM. RESULT---			3
Glucose	5.2	$\frac{\text{mmol}}{\text{L}}$	
Food	100	g	
►EST. Units	6.6	u	
Meal.	6.6	u	
Added	-0.0	u	
Active	0.0	u	

After checking the estimation record and confirming that it is correct, press **ACT** to directly enter the high-dose infusion screen, and the calculated result is also directly assigned, and press **ACT** to execute after confirmation.

Notice:

- The dosage calculated by the high-dose wizard can only be used as a reference for treatment, and the specific dosage must be fully evaluated according to the current situation or consult your attending physician.

# Charge-Exhaust

## Contents of this chapter

- **Screw reset (charging)**
  - screw reset
  - Refill into insulin pump
- **Propulsion-Exhaust**
- **Daily Total Review**
- **Exhaust Review**
- **Alarm review**

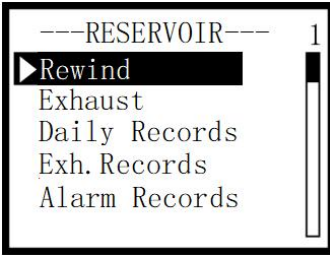
## Charge - Exhaust

### Screw reset (charging)

#### Screw Reset

Before the screw is reset, be sure to turn counterclockwise to remove the infusion line, take out the old pen core, and then perform the screw reset. Make sure it has been reset successfully before loading the refill.

Main Menu > Charge - Exhaust > Screw Reset



Press the ACT screw to reset and start execution. During the execution process, it cannot be stopped artificially or other operations are performed. The screen status is as follows:



After the reset is successful, the device will

## Charge - Exhaust

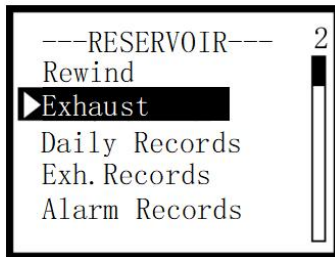
stop automatically, and a prompt screen of "Reset is complete, please put in the refill!!!" will appear.

### Install the cartridge and infusion line

1. Check the refill package, make sure it is within the validity period and undamaged, then tear open the package and take out the refill.
2. Put the refill into the refill compartment.
3. Install the infusion line on the insulin pump.

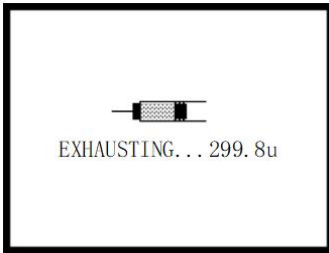
## Propulsion - Exhaust

Main Menu>Charge-Exhaust>Propulsion-Exhaust



Press  , the screen will display "Confirm that the pipeline is out of the human body, press ACT to start exhaust, press  to return". After confirming that the infusion line is not connected to the human body, press  again and an exhaust screen will appear.

## Charge - Exhaust



During execution, carefully observe the exhaust of the entire pipeline to ensure that all air bubbles in the pipeline have been exhausted. Exhaust for the first time after successful reset. Press **ACT** and the insulin pump will continue to exhaust for 40u. During this period, the exhaust process can be terminated by pressing the **←** or **ACT**. Afterwards, continue to press **ACT** to exhaust again.

Notice:



- Before performing "push-exhaust", the infusion needle must be separated from the human body.
- Do not perform the exhaust operation multiple times without a cartridge installed, as this may damage the insulin pump.
- Do not take out the battery directly after the screw reset successfully, and be sure to perform a "push--exhaust" operation before that.

### Daily records

Main Menu > Charges - Venting > Daily Totals Review

## Charge - Exhaust



```
---DAILY RECORDS---  
0313> 48 u  
0312> 46 u  
0310> 45 u  
0309> 46 u  
0308> 48 u  
0307> 47 u
```

The daily total volume review recorded the total daily volume of the last 500 daily infusions, which can be viewed by scrolling by pressing 、 .

### Exhaust records

Main Menu > Charges - Exhaust > Exhaust Review

```
---EXH. RECORDS---  
0315 08:10> 12 u  
0310 18:05> 15 u  
0305 12:30> 14 u  
0228 08:30> 12 u  
0223 18:20> 14 u  
0218 13:00> 13 u
```



Exhaust review records the latest 500 detailed exhaust information, which can be viewed by scrolling by pressing 、.

## Charge - Exhaust

### Alarm records

Main Menu > Charge - Exhaust > Alarm Review

---ALARM RECORDS---		
0315	06:10>	SUS
0315	06:05>	BLK
0314	17:30>	REW
0309	08:30>	REV
0308	18:20>	SUS
0301	10:03>	REW

The alarm review records the latest 500 low battery, reset, low drug, blockage and other alarm information, which can be viewed by scrolling by pressing  

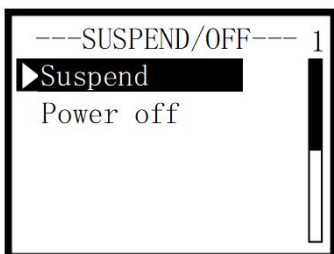
## Parameter Settings

# suspend/shutdown

After the built-in lithium battery is charged or loaded into the dry battery, the system will automatically start working, under normal circumstances, there is no need to stop in the middle, but sometimes it is necessary to accept the high magnetic field inspection, or in other special occasions are not suitable for continued infusion, then the equipment can be suspended and then removed, to avoid the waste of liquid, and the original infusion can be continued when the conditions are suitable. Infusion pauses will be discontinued including current basal rate infusions and ongoing high-dose infusions, and insulin pumps will not perform insulin infusions after pause until infusion is resumed.

### Infusion Suspend

Main Menu > suspend/Shutdown > Infusion Pause



Enter the main menu, press 、 , make "►" point to "Pause/Shutdown", press to confirm, enter the "Pause/Shutdown" page, select "Infusion Pause", press to confirm, then "Press ACT Pause the infusion, Press to return", and then press to confirm. The status of the screen

## Parameter Settings

after pausing is as follows:











After the system pauses, do not perform any settings or operations, press ACT and follow the system prompts to resume the infusion.

Notice:

- While you're off your insulin pump, your body still needs insulin. If more than 1 hour has passed since the pump was taken off, another method must be used to replenish insulin or the insulin pump must be put back on. When it is necessary to turn off the insulin pump for several days, other methods of stabilizing blood sugar must be agreed with the doctor.

### Shut down

Main Menu > Pause/Shutdown > Shutdown

Enter the main menu, press   , make "►" point to "Pause/Shutdown", press  to confirm, enter the "Pause/Shutdown" page, press   , make "►" point to "Shutdown", press  Confirm, then there will be "press  to confirm shutdown, press other to cancel; long press  to boot".

# Parameter settings

Contents of this chapter

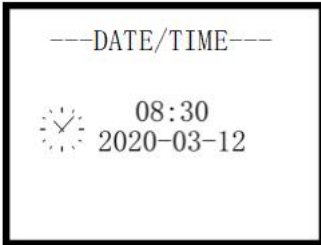
- Time setting
- Alarm settings
- Alert Settings
- Bluetooth settings (only for versions with Bluetooth function)
- Factory reset

# Parameter Settings

## Time setting

Only by setting the date and time correctly can the accurate infusion of the insulin pump be effective, so the time must be calibrated regularly.

Main menu>setting menu>time setting

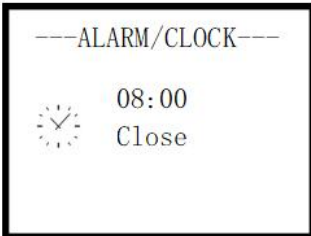


Enter the time setting screen, press 、 to select the modification item, press 、 , to modify the value of the highlighted item, press to switch the item pointed by the highlighted cursor, press to save and exit after setting.

## Alarm setting(optional)





This insulin pump has an alarm function, which can be set as a day or daily alarm reminder.

Main Menu>Parameter Settings>Alarm Settings



Enter the alarm setting screen, press 、 to select the

## Parameter Settings

modification item, press 、 to modify the value of the highlighted item, press  to switch the item pointed by the highlighted cursor, press  to save and exit after setting.

### Alert settings

Buzzer prompts: power on, alarm, blockage, end of medicine, low battery alarm, low medicine dose, meal reminder, when this reminder function is turned on, all reminder functions will have sound.

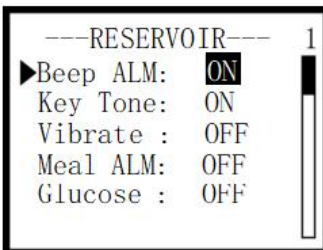
Button sound: After it is turned on, every time a button is pressed, there will be a "beep".

Vibration alarm: power on, alarm, blockage, end of medicine, low battery alarm, low medicine dose, and meal reminder. When this reminder function is turned on, all reminder alarm functions have vibration. The alarm still vibrates when the battery is empty, blocked, or low battery.







Meal reminder: After it is turned on, it will remind you to eat within the specified time after the high-dose infusion is over.

Blood sugar test reminder: After it is turned on, it will prompt to test blood sugar within the specified time after the high-dose infusion is over.

Main Menu>Parameter Settings>Alarm Settings



## Parameter Settings

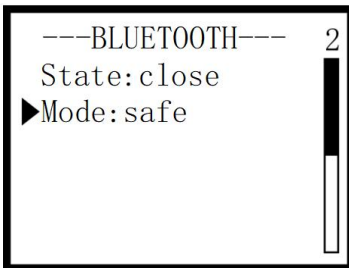
After entering the alarm setting screen, you can press 、 , to select the item to be modified, press 、 , to modify the option of the highlighted item, press  to switch the item pointed by the highlighted cursor, and press  to save and exit after setting.






### **Bluetooth settings (only for versions with Bluetooth function)**

Bluetooth status: When turned off, Bluetooth is off; when half-open, Bluetooth is off during 00:00-06:00, and is on during 06:00-24:00; when fully on, Bluetooth is 24 hours a day inside is open.

Operation mode: In safe mode, all operations need to be authorized by the pump end; in convenient mode, the operation only needs to obtain the first operation authorization of the pump end.

Main Menu>Parameter Settings>Bluetooth Settings



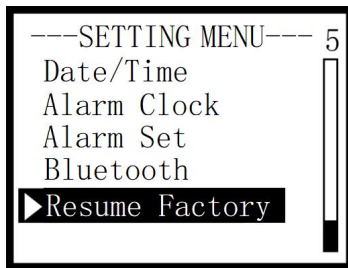
After entering the Bluetooth setting screen, you can adjust the item indicated by "▶" by pressing 、 , and then switch its status by pressing 、 , and then press  to exit.





## Parameter Settings

Note: For detailed operation methods of the Bluetooth function, please refer to the attachment "Insulin Pump Instruction Manual - APP User Guide".

### Factory reset

Main menu>Parameter setting>Restore factory settings



Enter the restore factory settings screen, and then the screen prompts to enter the password, press 、 to modify the number indicated by the reversed cursor, press  to switch the position indicated by the reversed cursor in turn, press  to move the cursor forward or exit this session operate.



Restore factory default password: 1234

Notice:

## Parameter Settings

- After performing this operation, all settings and values will be restored to the factory default state, including the limit value of the parameters set by the doctor.
- The total amount of drugs infused on that day will be reset and will not be saved in the daily total amount review record.

# Physician setting

## Contents of this chapter

- Insulin type
- Bolus MAX
- Basal MAX
- Daily MAX
- Base segment
- Three meals mode
- Pulse period
- Blocking sensitivity
- Custom Menu

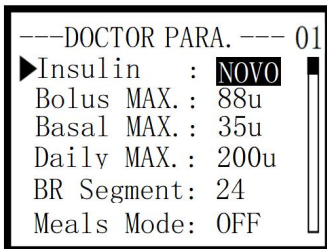
## Physician setting






Main Menu > Parameter Setting > Doctor Setting Parameters



Doctor setting parameter password: 5678

After entering the password, enter the doctor setting parameter screen.



After entering the doctor setting parameter screen, press   , to adjust the item indicated by "▶", and press   to adjust the value of the set parameter. Press  Save and Exit when finished.

The type of refill can be selected from "Novo" and "Others". Users can choose to purchase refills according to their own needs. For the matching refills, please refer to the table "Information of

## Physician setting

### Infusion Tubes and Insulin Refills Used Together"

Large dose limit setting range: default 20u, setting range 0 ~ 88u.

Base rate limit setting range: default 5 u/h, setting range is 0~35u/h.

Daily total limit setting range: default 60u, setting range 0~200u.

Please ask your doctor to determine this parameter according to your condition to ensure that even if there is a wrong operation or incorrect use by an incomplete person, the blood sugar fluctuations caused by it are within a controllable range to prevent life-threatening.

There are two options of 24-segment and 48-segment for the basic rate, which can be set by the user according to the treatment needs and usage habits.

After the three-meal mode is turned on, it will change to the three-meal mode on the manual large-dose infusion screen.

Pulse cycle, set the interval time of each infusion pulse of large dose, the default is 5 seconds, the time can be extended

## Physician setting

appropriately for people with sensitive skin and thin people, so as to avoid induration at the infusion puncture site.

Blocking sensitivity can be divided into 3 levels, high, medium, and low, so that the appropriate sensitivity can be selected according to individual use.

The menu option allows the user to freely open or close some of the menus as needed, so that it is more convenient during normal use.

### **Menu option default state:**

Square/Double Wave High Dose	On
Three meals preset	On
Bolus Wizard	Off
Fast base rate setting	On
Temporary base rate setting	ON
Basic rate plan	On
Corrected Base Rate	Off
Alarm setting	Off
Alert Settings	On


# Other information

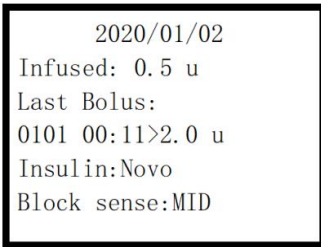
Contents of this chapter

- Infusion Basic Information Query
- Device information query

## Other information



### Infusion Basic Information Query

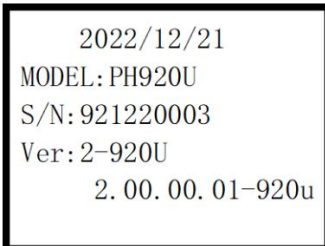
On the main display screen, directly press  to enter the basic information quick query screen, where you can query the current date, the amount of medicine infused on that day, the latest large-dose infusion, the type of cartridge and the sensitive information on blockage.



```
2020/01/02
Infused: 0.5 u
Last Bolus:
0101 00:11>2.0 u
Insulin:Novo
Block sense:MID
```

### Device Information Query

After entering the basic information quick query screen, press   directly to enter the device model information screen, where you can query the device model, device number and software version and other information.



```
2022/12/21
MODEL: PH920U
S/N: 921220003
Ver: 2-920U
2.00.00.01-920u
```

# Handling of alarms, prompts and faults

Contents of this chapter

- **Alarm overview**
- **Troubleshooting**

## Handling of alarms, prompts and faults

### **Alarm overview**

The insulin pump produced by PHRAY Technology Co., Ltd. adopts a dual-CPU mutual inspection design, which can perform hundreds of thousands of automatic mutual inspections every day to ensure the safe and stable operation of the equipment. If an abnormal condition requiring immediate attention is detected, the insulin pump will send out a warning message through the alarm. At the same time, an alarm log is formed. The alarm log is automatically saved when the power is cut off, and the alarm log is still saved after a long time of complete power failure.

### **Alarm system check**

When the device is powered on, the device will automatically detect the alarm system. If you feel the vibration and hear the beep sound, it means that the vibration alarm system of the device is operating normally; otherwise, please check whether there is any problem with the device.

### **Alarm delay**

Because it takes a certain amount of time for signal transmission and signal processing between alarm systems, there is a delay of  $t_0$  between each alarm signal and the alarm state, and the delay of detecting the alarm state and issuing the alarm time is  $t_0 < 5s$  according to the signal transmission capture test.

### **Alarm presets**

Using different alarm presets for insulin pumps can be potentially dangerous. Users should set appropriate blocking retribution presets based on their personal usage.

## Handling of alarms, prompts and faults

Inappropriate alarm presets can cause false alarms that block alarms. Conditions such as hypoglycemia.

### **Why the alerts alarm are important**

The insulin pump can monitor the entire operating program. Sometimes an alarm will be issued when some special functions are turned on. Some alarms are normal prompts in the working of the insulin pump. For example, an alarm will be issued when the liquid medicine in the pen core is used up or the battery is low, so that the medicine liquid and the battery can be replaced in time. Therefore, the alarm is also the basic guarantee for effective and safe use of insulin pumps for treatment.

### **What should I do if I receive an alarm?**

When the insulin pump vibrates to alert:

- Check the screen status to understand the cause of the alarm.
- Follow the prompts on the screen, press  or  to clear the alarm.

After the button is pressed to eliminate the current alarm, an icon will be displayed on the screen, which indicates that the interval between the alarm and the next alarm detection is 15 seconds.

### **Alarm status priority**

After product risk management analysis, according to the degree of harm caused by each alarm state, the following alarm state priorities are obtained:

The following alarm signals are all latch signals

- High priority alarm

## Handling of alarms, prompts and faults

Large Force!!! Please Check

NO TANK! ! ! Please Check

- Medium priority alarms
  - BLOCKED!! Please Check
  - EMPTY RESERVOIR!! Please fill it
- Low priority alarm
  - Batteries! update ASAP
- Suggestive signal
  - (1) Super daily total reminder
  - (2) Dining tips
  - (3) Blood sugar test tips

Alarm volume: 45-80dB(A) at a distance of 1m

### Alarm reason

- **Alarm for empty reservoir when there is no infusion solution**



If this alarm occurs, you need to check the remaining amount of insulin in the cartridge, and replace the insulin at an appropriate time or immediately, and make sure to carry a new set of cartridges and infusion lines with you.

## Handling of alarms, prompts and faults

- Blockage alarm before the infusion line blockage reaches the threshold value.



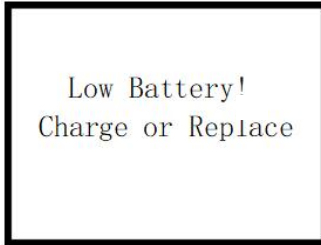
Time required for blocking alarm to trigger

Device parameters	Pill dosage 6u ) Blocking alarm maximum time	Pill dosage 4u ) Blocking alarm maximum time	Maximum blocking pressure
Run at medium speed 15u/h	40minute	25minute	200kp

If the blockage of the infusion line reaches the blockage value before the blockage alarm, please follow the steps below:

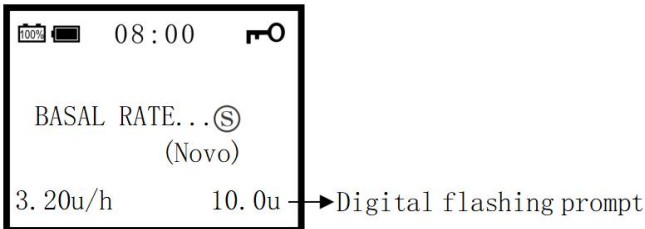
- (1) Check whether the infusion of the drug solution is complete
  - (2) Check for kinked infusion tubing;
  - (3) Replace the infusion line;
  - (4) Replacement battery;
  - (5) If the alarm still occurs after following the above steps, please call the 24-hour service hotline.
- **voltage prompt**

## Handling of alarms, prompts and faults



If this alarm occurs on the lithium battery, it means that the battery is exhausted, and it must be connected to the power supply for charging in time; if this alarm occurs on several batteries, it indicates that the battery is exhausted, and a new battery must be inserted into the insulin pump. When installing, pay attention to the negative end first. Lithium battery working time  $\geq 7$  days, dry battery working time  $\geq 7$  days (battery performance and frequency of use affect working time)

- **When the medicine solution is lower than 20u, the low medicine solution prompts**



- **A meal reminder is issued after the bolus infusion ends. (Dining reminder must be turned on)**
- **A blood glucose test reminder is issued after the dose infusion is completed. (Measurement of blood sugar must be turned on)**

## Handling of alarms, prompts and faults

- **Tips for exceeding the daily total amount**



Carefully confirm if a bolus is needed and make sure it is at the correct value. If you need to increase the dose, you need to seek the advice of the attending doctor and change the high dose and daily total limit in the parameters set by the doctor.

Remove refill alarm:

Under the normal infusion of the device, remove the insulin refill, the device will produce an alarm signal, please check.

## Troubleshooting

- **There is no display on the screen or the machine is switched on and off automatically**

When there is no display on the screen or automatic repeat switch, please check whether the battery is low and replace the battery.

- **Insulin pump dropped**

(1) Confirm that the main body of the shell is in good condition without cracks or damage;

(2) Confirm that the information displayed on the screen is normal;

## Handling of alarms, prompts and faults

(3) Confirm that the alarm system works normally (the vibration function is normal when the equipment is turned on);

(4) please call the 24-hour service hotline.

### ● **Insulin pump water**

If the insulin pump falls into water or gets water, please do the following:

(1) Gently wipe off the water on the shell with a soft towel;

(2) Open the cover of the refill compartment and check whether there is water in the refill compartment. If there is water, please dry it in time;

(3) Check whether there is water in the battery compartment, and if so, please dry it immediately before using it.

(4) Do not use hot air to dry, otherwise it may damage the electronic components in the insulin pump.

(5) If it cannot be used normally after being wiped dry, remove the refill compartment cover and battery cover, put the refill compartment of the insulin pump upwards, and let it dry naturally in a cool, dry place.

### ● **Treatment of abnormal blood sugar**

Please check your blood sugar after the insulin pump alarm is dealt with or when you feel unwell. If the blood sugar is lower than the normal value, pull out the infusion needle immediately, eat about 15 grams of sugar first, then contact your doctor, measure your blood sugar every hour before the doctor gives advice on how to deal with it, eat about 15 grams of sugar until the blood sugar so far. If the blood sugar is higher than the target value, please use the

## Handling of alarms, prompts and faults

high-dose guide to inject additional insulin doses. If ketoacidosis occurs or the blood sugar is higher than 16.7mmol/L, immediately inject 20% of the total daily insulin into the skin and contact your Doctor, repeat the subcutaneous injection every 2-3 hours before the doctor gives treatment advice, and check the blood sugar every 1-2 hours. The appropriate rate of blood sugar drop is 10%-15% per hour until the blood sugar is normal.

- **Other**

If there is a fault that cannot be solved, please contact our company's professional and technical personnel for maintenance, and do not open the casing or repair the operation by yourself.

If you need a circuit diagram and a list of components, please contact our company for a request.

# **Electromagnetic compatibility**

Contents of this chapter

- **Electromagnetic  
compatibility-related considerations**
- **warning**
- **schedule**

# Electromagnetic Compatibility

## Electromagnetic compatibility-related considerations

- PH900 series insulin pump meets the relevant requirements of YY0505/IEC60601-1-2 standard electromagnetic compatibility.
- PH900 series insulin pumps meet the relevant requirements of GB 4824/CISPR 11 Group I Class B.
- This instruction manual specifies the expected electromagnetic environment and related warning content for the use of PH900 series insulin pumps, and the user needs to use this equipment according to the electromagnetic compatibility information provided.
- The purchaser or user of the PH900 series insulin pump should use the insulin pump in the electromagnetic environment specified in Table 201, 202, 203, 205, otherwise it may cause the insulin pump to not work properly.
- Portable and mobile RF communication devices may interfere with the normal use of the PH900 series insulin pumps, please use them in the recommended electromagnetic environment.
- Medical personnel are trained for on-site installation and use based on the EMC information provided in the table below.
- For example, the use of accessories and other components outside the regulations with the PH900 series insulin pump may result in an increase in the emission of the device or a decrease in the immunity of the device.

# Electromagnetic Compatibility

## **Warning**

- With the exception of parts and cables sold by the manufacturer of the PH900 series insulin pump as spare parts for internal components, the use of accessories, parts, and cables not specified may result in increased emissions or reduced noise immunity of the PH900 series insulin pumps.
- The PH900 series insulin pump should not be used in close proximity or stacking with other devices, and if it must be used in close proximity or stacking, it should be observed and verified to function properly in the configuration it is using.

# Electromagnetic Compatibility

## schedule

**Table 201**

Guidelines and Manufacturer's Statement – Electromagnetic Emission		
The PH900 series insulin pumps are intended to be used in the following electromagnetic environments, and the purchaser or user warrants that they are used in such electromagnetic environments:		
Electromagnetic emission	compliance	Electromagnetic Environment – A Guide
Radio-Frequency Emissions	1 set	The PH900 series insulin pumps use RF energy for their internal functions only. As a result, it has low RF and little chance of interference with nearby electronics.
Radio-Frequency Emissions	Category B	The PH900 series insulin pumps are suitable for use in all facilities, including domestic facilities and direct connection to the residential public low-voltage power grid.
Harmonic Emissions	Category A	
Voltage fluctuation/flicker emission	conform	

# Electromagnetic Compatibility

**Table 202**

Guidelines and Manufacturer's Statement – Electromagnetic Immunity			
The PH900 Series Insulin Pump is intended to be used in the electromagnetic environment specified below, and the purchaser or user warrants that it will be used in such an electromagnetic environment:			
Immunity test	Test level	Conform to the level	Electromagnetic Environment – A Guide
Electrostatic discharge	±8 kV Contact discharge ±15kV Air discharge	±8 kV Contact discharge ±15kV Air discharge	The floor should be wooden, concrete or tile, and if the floor is covered with synthetic material, the relative humidity should be at least 30%
Electrically fast transient bursts	±2 kV to the power cord ±1 kV to the input/output lines	±2 kV to the power cord  not applicable	power supply should be of the quality typical of a commercial or hospital environment
surge	±1 kV Wire-to-wire ±2 kV Line-to-earth	±1 kV Wire-to-wire not applicable	The grid power supply should be of the quality typical of a commercial or

## Electromagnetic Compatibility

			hospital environment
Voltage sags, short interruptions, and voltage changes on the power input line	<p>&lt;5% UT, Lasts 0.5 cycles (On UT, &gt; 95% sag)</p> <p>40% UT, Lasts 5 cycles (On UT, there is a 60% slip)</p> <p>70% UT, Lasts 25 cycles (On UT, On UT, there is a 30% slip)</p> <p>&lt;5% UT, Lasts 5s (On UT, &gt; 95% sag)</p>	<p>&lt;5% UT, Lasts 0.5 cycles (On UT, &gt; 95% sag)</p> <p>40% UT, Lasts 5 cycles (On UT, there is a 60% slip)</p> <p>70% UT, Lasts 25 cycles (On UT, On UT, there is a 30% slip)</p> <p>&lt;5% UT, Lasts 5s (On UT, &gt; 95% sag)</p>	<p>The grid power supply should be of the quality typical of a commercial or hospital environment.</p> <p>If users of the PH900 series insulin pumps require continuous operation during power outages, the PH900 insulin pumps are recommended to be powered by an uninterruptible power supply or battery</p>
Power frequency magnetic field (50 Hz/60 Hz)	400 A/m	400 A/m	The power frequency magnetic field should have the horizontal characteristics of the power

# Electromagnetic Compatibility


			frequency magnetic field typical of a typical place in a typical commercial or hospital environment
UT refers to the AC network voltage before the test voltage is applied.			

# Electromagnetic Compatibility

**Table 203**

Guidelines and Manufacturer's Declarations – Electromagnetic Immunity			
The PH900 insulin pump is intended for use in the following electromagnetic environment, and the purchaser or user should ensure that it is used in such an electromagnetic environment:			
Immunity test	IEC 60601 Test level	Conform to the level	Electromagnetic Environment—Guide
RF conduction	3V (RMS) 150 kHz~80 MHz(In addition to the engineering and medical frequency bands)	10 V	Portable and mobile RF communication devices should not be placed closer together than the recommended isolation distance Use any part of the PH900 insulin pump, including cables.This distance should be calculated by the formula corresponding to the transmitter frequency. Recommended isolation distance
RF radiation	10 V (RMS) 150 kHz~80 MHz (Engineering and medical frequency)	10 V/m	$d=0.35\sqrt{P}$ $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz~800MHz $d=2.3\sqrt{P}$

# Electromagnetic Compatibility

	<p>bands )</p> <p>10 V/m</p> <p>80 MHz~2.5 GHz</p>	<p>800MHz~2.5GHz</p> <p>The maximum output power rating of the transmitter is based on the transmitter manufacturer, measured in watts (W).</p> <p>d—Recommended isolation distance, measured in meters (m).</p> <p>The field strength of a fixed RF transmitter is determined by an electromagnetic site survey and should be lower than the coincidence level in each frequency range.</p> <p>Interference may occur near devices marked with the following symbols.</p> 
<p>Note 1: At the 80 MHz and 800 MHz frequency points, the formula for the higher frequency band is used.</p> <p>NOTE 2: These guidelines may not be suitable for all situations, and electromagnetic propagation is affected by absorption and reflection by buildings, objects, and the human body.</p>		
<p>a The engineering and medical frequency band between 150 kHz and 80 MHz refers to 6.765MHz~6.795MHz、13.553MHz~13.567MHz、26.957MHz~27.283MH</p>		

## Electromagnetic Compatibility

and 40.66MHz~40.70MHz.

b The coincidence level in the engineering and medical frequency band between 150 kHz~80 MHz and the frequency range of 80 MHz~2.5 GHz is used to reduce the possibility of interference caused by mobile/portable communication devices accidentally introduced into the patient area. For this purpose, an additional factor of 10/3 is used to calculate the recommended isolation distance for transmitters in these frequency ranges.

c The field strength of fixed transmitters, such as base stations for wireless (cellular/cordless) telephones and terrestrial mobile radios, amateur radios, AM and FM radio broadcasts, and television broadcasts, cannot be accurately predicted in theory. In order to assess the electromagnetic environment of a fixed RF transmitter, the survey of the electromagnetic site should be considered. If the PH900 pump is found to be located at a field strength higher than the applicable RF coincidence level above, the PH900 pump should be observed to verify that it is functioning properly. If abnormal performance is observed, supplemental measures may be necessary, such as reorienting or repositioning the PH900 series insulin pumps.

d In the entire frequency range of 150 kHz~80 MHz, the field strength should be less than 10 V/m.

# Electromagnetic Compatibility

**Table 205**

	Recommended isolation distance between portable and mobile RF communication devices and PH900 series insulin pumps				
	The PH900 series insulin pumps are intended for use in electromagnetic environments where RF radiation disturbance is controlled. Depending on the maximum rated output power of the communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile RF communication equipment (transmitter) and the PH900 series insulin pump recommended below.				
The maximum rated output power of the transmitter W	Corresponds to the isolation distance of the transmitter at different frequencies/m				
	150kHz~80MHz (In addition to the engineering medical frequency band) $d=0.35\sqrt{P}$	150kHz~80MHz (Engineering Medical Frequency Band) $d=1.2\sqrt{P}$	80MHz ~800MHz $d=1.2\sqrt{P}$	800MHz ~2.5GMHZ $d=2.3\sqrt{P}$	
0.01	0.035	0.12	0.12	0.23	
0.1	0.11	0.38	0.38	0.73	
1	0.35	1.2	1.2	2.3	
10	1.1	3.8	3.8	7.3	
100	3.5	12	12	23	
	For the maximum rated output power of the transmitter not listed in the table above, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where P is the maximum rated output power of the transmitter				

## Electromagnetic Compatibility

provided by the transmitter manufacturer, in watts (W).

Note 1: At the 80 MHz and 800 MHz frequency points, the formula for the higher frequency bands is used.

Note 2: The engineering and medical frequency band between 150 kHz and 80 MHz refers to 6.765MHz ~ 6.795MHz、13.553MHz ~ 13.567MHz、26.957MHz ~ 27.283MHz and 40.66MHz ~ 40.70MHz.

Note 3: Additional factor 10/3 is used to calculate the recommended isolation distance for transmitters in the 150 kHz ~ 80 MHz frequency band and 80 MHz ~ 2.5 GHz frequency range to reduce the possibility of interference caused by portable/mobile communication devices when accidentally introduced into the patient area.

Note 4: These guidelines may not be suitable for all situations, and electromagnetic propagation is affected by absorption and reflection by buildings, objects, and the human body.

# Technical Parameters

1. **By anti-shock type:** Class II internal power supply
2. **Classification according to the degree of electric shock protection:** BF type application part
3. **Size:** 99mm\*47mm\*20mm Tolerances  $\pm 5\text{mm}$
4. **Basic rate segmentation:** 24/48 segments
5. **Minimum dose per dose:** 0.05 u (1U is equal to 0.01 ml)
6. **Infusion methods:** basic infusion, Temporary Basal Infusion, high-dose infusion, prescription/double wave infusion.
7. **Basic rate setting range:** 0~35u/h, medium speed 15u/h
8. **Basal rate infusion tolerance:**  $\pm 5\%$  or  $\pm 0.01\text{u/h}$
9. **Temporary rate setting range:** the speed setting range is 0-200% of the base rate setting value, and the duration setting range is 0-24 hours.
10. **Large dose setting range:** 0 ~ 88u.
11. **Large dose infusion tolerance:**  $\pm 5\%$
12. **Large dose setting mode:** regular mode, three meal mode, square/double wave mode
13. **Square/double wave setting range:** the infusion dose setting

## Parts List

range is 2~88u; the time setting range is 0~240 minutes; the fast infusion setting range is 0~90%, and the stepping amount is 10%.

14. **Maximum daily total amount:** 200u

15. **Screw reset form:** motor drive

16. **Alarm mode:** vibration

17. **Warning items:**

- a) Reminder for meal after high-dose infusion;
- b) Low liquid prompt when the liquid is lower than 20u;
- c) Alarm after the end of medicine: the screen is visible "The medicine is finished!! Please charge the charge in time", accompanied by intermittent (5s interval) vibration alarm;
- d) The infusion pipeline is sensitive to blockage, and the high, medium, and low should be blocked before reaching 4U, 5U, and 6.5U respectively!!. words, accompanied by intermittent (5s interval) vibration alarm;
- e) At least 30 minutes before the infusion is stopped before the battery is depleted, there is a continuous visual and intermittent (10 minute interval) vibration alarm; At least 3min

## Parts List

before the battery is depleted, the device should stop infusion;

18. **Number of CPUs:** Dual CPUs
19. **Refill volume:** 3.0ml
20. **Infusion line interface form:** PH2 interface
21. **Battery type:** polymer lithium ion battery 3.7V, 220mAh or DC1.5V±0.2V (AAA battery)
22. **Wireless data interface:** Bluetooth
23. **Conditions of use:** ambient temperature +5°C~+40°C, relative humidity 15%~90%, atmospheric pressure 700hPa~1060hPa.
24. **Storage conditions:** ambient temperature -20°C ~ 55°C, 10~90%R.H. (non-condensing), atmospheric pressure 700hPa~1060hPa.
25. **IP rating:** IP67.

## Parts List

# Accessories list

1. Main device
2. Holsters
3. Battery cover key
4. Spare battery cover
5. Manual
6. Warranty card
7. Certificate of Conformity
8. Factory inspection report

## Parts List

Information on infusion lines and insulin refills used with the

Infusion tubing

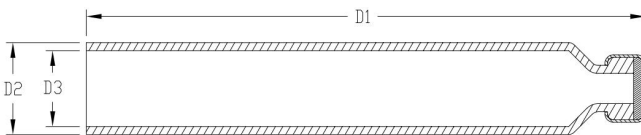
Company	Product Name	Model
Zhengzhou Phray Technology Co., Ltd	Disposable infusion set for insulin pumps	ECS-45C、ECS-65C、ECL-45C、ECL-65C、EKL-45C、EKL-65C、EKE-45C、EKE-65C、ECS-60C、ECS-90C、ECL-60C、ECL-90C、EKL-60C、EKL-90C、EKE-60C、EKE-90C

Insulin Cartridge:

3mL standard cartridge-type insulin vial , complying with ISO

11608-3, with the following dimensional

requirements:



## Parts List

	D1 (mm)	D2 (mm)	D3 (mm)
Novo Nordisk	66.4±0.2	∅11.1±0.15	∅9±0.15
Other types	64.2±0.2	∅ 11.7±0.15	∅9.5±0.15

Other types include insulin cartridges meeting the aforementioned requirements, such as those from Sanofi, Eli Lilly, and Gan & Lee.

# Attached table 1

A control table was set at the basal rate of short-acting insulin

Basic total \ Time	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40
0—1	0.1	0.2	0.2	0.2	0.3	0.4	0.4	0.4	0.5	0.5	0.6	0.7	0.7	0.7	0.8	0.8	0.8	0.9
1—2	0.2	0.2	0.3	0.3	0.4	0.5	0.5	0.6	0.6	0.7	0.7	0.8	0.8	0.9	1.0	1.0	1.1	1.2
2—3	0.2	0.3	0.4	0.5	0.5	0.5	0.6	0.7	0.8	0.8	0.9	0.9	1.0	1.1	1.2	1.2	1.3	1.4
3—4	0.3	0.5	0.5	0.7	0.6	0.7	0.8	0.9	1.0	1.1	1.1	1.2	1.4	1.4	1.5	1.6	1.7	1.8
4—5	0.4	0.6	0.7	0.9	0.9	1.1	1.3	1.4	1.6	1.7	1.8	1.9	2.1	2.2	2.5	2.6	2.7	2.9
5—6	0.5	0.7	0.8	1.0	1.2	1.4	1.5	1.6	1.8	2.0	2.1	2.3	2.5	2.6	2.8	3.0	3.1	3.3
6—7	0.4	0.6	0.7	0.8	0.9	1.1	1.2	1.2	1.5	1.6	1.7	1.8	2.0	2.1	2.3	2.4	2.5	2.7
7—8	0.3	0.4	0.5	0.5	0.6	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.8	2.0
8—9	0.3	0.3	0.3	0.4	0.5	0.5	0.6	0.7	0.8	0.9	1.0	1.0	1.0	1.1	1.1	1.2	1.3	1.3
9—10	0.2	0.2	0.3	0.4	0.5	0.5	0.6	0.7	0.7	0.8	0.9	1.0	1.0	1.1	1.1	1.2	1.3	1.3
10—11	0.2	0.2	0.3	0.4	0.5	0.5	0.6	0.7	0.7	0.8	0.9	1.0	1.0	1.1	1.1	1.2	1.3	1.3
11—12	0.2	0.2	0.3	0.4	0.5	0.5	0.6	0.7	0.7	0.8	0.9	1.0	1.0	1.1	1.1	1.2	1.3	1.3
12—13	0.2	0.2	0.3	0.4	0.5	0.5	0.6	0.7	0.7	0.8	0.9	1.0	1.0	1.1	1.1	1.2	1.3	1.3

Attached table 1

13—14	0.2	0.2	0.3	0.4	0.5	0.5	0.6	0.7	0.8	0.8	1.0	1.0	1.0	1.1	1.1	1.2	1.3	1.3
14—15	0.2	0.3	0.4	0.4	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.1	1.2	1.3	1.3	1.4	1.5	1.6
15—16	0.3	0.4	0.5	0.5	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0
16—17	0.3	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.9	2.0	2.1	2.2
17—18	0.3	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.9	2.0	2.1	2.2
18—19	0.3	0.3	0.5	0.6	0.6	0.8	0.8	0.9	1.0	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8
19—20	0.2	0.3	0.4	0.5	0.5	0.6	0.7	0.8	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.4	1.5	1.6
20—21	0.2	0.3	0.3	0.4	0.5	0.5	0.6	0.7	0.7	0.8	0.8	0.9	1.0	1.1	1.1	1.2	1.3	1.3
21—22	0.2	0.2	0.3	0.4	0.5	0.5	0.6	0.7	0.7	0.8	0.8	0.9	1.0	1.1	1.1	1.2	1.3	1.3
22—23	0.2	0.2	0.3	0.3	0.4	0.5	0.5	0.5	0.6	0.7	0.7	0.8	0.9	0.9	0.9	1.0	1.0	1.1
23—24	0.1	0.2	0.2	0.2	0.3	0.4	0.4	0.4	0.5	0.5	0.6	0.6	0.7	0.7	0.8	0.8	0.8	0.9

## Attached table 2

A comparison table was set for rapid-acting (ultra-short-acting) insulin basal rates

Basic total \ Time	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40
1—2	0.1	0.2	0.2	0.2	0.3	0.4	0.4	0.4	0.5	0.5	0.6	0.7	0.7	0.7	0.8	0.8	0.8	0.9
2—3	0.2	0.2	0.3	0.3	0.4	0.5	0.5	0.6	0.6	0.7	0.7	0.8	0.8	0.9	1.0	1.0	1.1	1.2
3—4	0.2	0.3	0.4	0.5	0.5	0.5	0.6	0.7	0.8	0.8	0.9	0.9	1.0	1.1	1.2	1.2	1.3	1.4
4—5	0.3	0.5	0.5	0.7	0.6	0.7	0.8	0.9	1.0	1.1	1.1	1.2	1.4	1.4	1.5	1.6	1.7	1.8
5—6	0.4	0.6	0.7	0.9	0.9	1.1	1.3	1.4	1.6	1.7	1.8	1.9	2.1	2.2	2.5	2.6	2.7	2.9
6—7	0.6	0.7	0.8	1.0	1.2	1.4	1.5	1.6	1.8	2.0	2.1	2.3	2.5	2.6	2.8	3.0	3.1	3.3
7—8	0.4	0.6	0.7	0.8	0.9	1.1	1.2	1.2	1.5	1.6	1.7	1.8	2.0	2.1	2.3	2.4	2.5	2.7
8—9	0.3	0.4	0.5	0.5	0.6	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.8	2.0
9—10	0.3	0.3	0.3	0.4	0.5	0.5	0.6	0.7	0.8	0.9	1.0	1.0	1.0	1.1	1.1	1.2	1.3	1.3
10—11	0.2	0.2	0.3	0.4	0.5	0.5	0.6	0.7	0.7	0.8	0.9	1.0	1.0	1.1	1.1	1.2	1.3	1.3
11—12	0.2	0.2	0.3	0.4	0.5	0.5	0.6	0.7	0.7	0.8	0.9	1.0	1.0	1.1	1.1	1.2	1.3	1.3
12—13	0.2	0.2	0.3	0.4	0.5	0.5	0.6	0.7	0.7	0.8	0.9	1.0	1.0	1.1	1.1	1.2	1.3	1.3

## Attached table 2

13—14	0.2	0.2	0.3	0.4	0.5	0.5	0.6	0.7	0.7	0.8	0.9	1.0	1.0	1.1	1.1	1.2	1.3	1.3
14—15	0.2	0.2	0.3	0.4	0.5	0.5	0.6	0.7	0.8	0.8	1.0	1.0	1.0	1.1	1.1	1.2	1.3	1.3
15—16	0.2	0.3	0.4	0.4	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.1	1.2	1.3	1.3	1.4	1.5	1.6
16—17	0.3	0.4	0.5	0.5	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0
17—18	0.3	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.9	2.0	2.1	2.2
18—19	0.3	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.9	2.0	2.1	2.2
19—20	0.3	0.3	0.5	0.6	0.6	0.8	0.8	0.9	1.0	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8
20—21	0.2	0.3	0.4	0.5	0.5	0.6	0.7	0.8	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.4	1.5	1.6
21—22	0.2	0.3	0.3	0.4	0.5	0.5	0.6	0.7	0.7	0.8	0.8	0.9	1.0	1.1	1.1	1.2	1.3	1.3
22—23	0.2	0.2	0.3	0.4	0.5	0.5	0.6	0.7	0.7	0.8	0.8	0.9	1.0	1.1	1.1	1.2	1.3	1.3
23—24	0.2	0.2	0.3	0.3	0.4	0.5	0.5	0.5	0.6	0.7	0.7	0.8	0.9	0.9	0.9	1.0	1.0	1.1
0—1	0.1	0.2	0.2	0.2	0.3	0.4	0.4	0.4	0.5	0.6	0.6	0.6	0.7	0.7	0.8	0.8	0.8	0.9

## Attached table 3

Comparison table of the effect of work-rest time correction parameters on automatic basal rate

Time Correction amount	0-1	1-2	2-3	3-4	4-5	5-6	6-7	7-8	8-9	9-10	10-11	11-12
-1	0.6	0.7	0.9	1.4	1.6	1.2	1.0	0.7	0.7	0.7	0.7	0.7
0	0.4	0.6	0.7	0.9	1.4	1.6	1.2	1.0	0.7	0.7	0.7	0.7
1	0.4	0.4	0.6	0.7	0.9	1.4	1.6	1.2	1.0	0.7	0.7	0.7
Time 校正量	12-13	13-14	14-15	15-16	16-17	17-18	18-19	19-20	20-21	21-22	22-23	23-24
-1	0.7	0.8	1.0	1.1	1.1	0.9	0.8	0.7	0.7	0.5	0.4	0.4
0	0.7	0.7	0.8	1.0	1.1	1.1	0.9	0.8	0.7	0.7	0.5	0.4
1	0.7	0.7	0.7	0.8	1.0	1.1	1.1	0.9	0.8	0.7	0.7	0.5



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